

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

ICOTYDE 200 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains icotrokinra hydrochloride equivalent to 200 mg icotrokinra.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet (tablet).

Yellowish orange to yellowish brown, oval film-coated tablet, approximately 19 mm in length and 9 mm in width debossed with '200' on one side and 'JNJ' on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ICOTYDE is indicated for the treatment of moderate to severe plaque psoriasis in adults, and adolescents 12 years of age and older and weighing at least 40 kg, who are candidates for systemic therapy.

4.2 Posology and method of administration

Treatment should be initiated under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque psoriasis.

Adults and adolescents weighing at least 40 kg

The recommended dose of ICOTYDE is 200 mg orally once daily on an empty stomach (see Method of administration).

If a patient shows no evidence of therapeutic benefit after 24 weeks, treatment discontinuation should be considered. The patient's response to treatment should be evaluated on a regular basis. Some plaque psoriasis patients with initial partial response may subsequently improve with continued treatment beyond 24 weeks.

Missed dose

If a dose is missed, patients should be instructed to take the dose on the same day as soon as possible and then resume normal dosing schedule the following day.

Special populations

Elderly

No dose adjustment is required in elderly patients aged 65 years and older (see section 5.2).

Renal impairment

No dose adjustment is recommended for patients with mild, moderate or severe renal impairment. ICOTYDE has not been studied in patients with end-stage renal disease and should only be used in these patients if the benefit outweighs the possible risk (see section 5.2).

Hepatic impairment

No dose adjustment is recommended in patients with mild, moderate, or severe hepatic impairment (see section 5.2).

Paediatric population

In children aged 12 years to less than 18 years and weighing at least 40 kg, the recommended dose is the same as in adults (see above).

The safety and efficacy of ICOTYDE in children younger than 12 years of age or children weighing less than 40 kg have not yet been established. No data are available.

Method of administration

For oral use.

ICOTYDE film-coated tablets should be taken upon waking on an empty stomach with water at least 30 min before eating food (see section 5.2). Film-coated tablet must be swallowed whole.

Alternative method of administration

For patients who have difficulty swallowing tablets whole, ICOTYDE 200 mg film-coated tablet can be dispersed in water.

Patients should place one ICOTYDE 200 mg film-coated tablet in a cup containing at least 120 mL of water. It may take a few minutes for the film-coated tablet to disperse. The film-coated tablet may not completely disperse. The mixture may look yellow, milky, or cloudy and small pieces may be seen in the water which are safe to swallow. The cup should be gently swirled before drinking. The full mixture should be swallowed.

Patients should fill the cup with at least an additional 120 mL of water to make sure the whole dose is taken and should swallow contents completely. ICOTYDE film-coated tablet should be taken as soon as possible after dispersion in water.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Clinically important active infections (e.g. active tuberculosis, see section 4.4).

4.4 Special warnings and precautions for use

Immunisations

No data on the response to immunisations under icotrokinra treatment are available. As a precautionary measure, prior to treatment initiation, completion of all age-appropriate immunisations according to the current immunisation guidelines should be considered. Administration of live vaccines is not recommended during treatment with icotrokinra and within 3 days after discontinuation of icotrokinra.

For recommendations on administration of live vaccines in newborns potentially exposed during pregnancy, see section 4.6.

Infections

Medicines that interact with the immune system may increase the risk of infection. Treatment should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated. Patients should be instructed to seek medical advice if signs or symptoms suggestive of a clinically relevant chronic or acute infection occur. If a patient develops such an infection and/or is not responding to standard therapy, monitor the patient closely and discontinue icotrokinra until the infection resolves.

4.5 Interaction with other medicinal products and other forms of interaction

Live vaccines/therapeutic infectious agents

Live vaccines should not be administered to patients during treatment with icotrokinra and within 3 days after discontinuation of icotrokinra (see sections 4.4 and 4.6).

Interaction with other medicinal products

No clinical drug-drug interaction studies with icotrokinra have been performed.

Based on *in vitro* studies, icotrokinra is not a CYP enzyme substrate, inhibitor, or inducer. Icotrokinra is not a substrate or inhibitor of P-glycoprotein (P-gp) or other major drug transporters. Therefore, no drug interactions are expected.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of icotrokinra in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

As a precautionary measure, it is preferable to avoid the use of ICOTYDE during pregnancy.

It is unknown if icotrokinra crosses the placenta. As a precautionary measure, administration of live vaccines to newborns potentially exposed to icotrokinra during pregnancy within the first 3 days after birth is not recommended. If there is a clear clinical benefit for the individual infant, administration of a live vaccine might be considered (see sections 4.4 and 4.5).

Breast-feeding

It is unknown whether icotrokinra/metabolites are excreted in human milk. Available pharmacokinetic data in animals have shown the presence of icotrokinra in the plasma of nursing rat pups (see section 5.3). A risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or discontinue/abstain from ICOTYDE therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility

The effect of icotrokinra on human fertility has not been evaluated. Animal studies do not indicate direct or indirect harmful effects with respect to fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

ICOTYDE has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions were fungal infections (1.1%).

Tabulated list of adverse reactions

Adverse reactions for icotrokinra from clinical studies are listed (see Table 1) by MedDRA System Organ Class and are based on the following conventions: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1\ 000$ to $< 1/100$); rare ($\geq 1/10\ 000$ to $< 1/1\ 000$); very rare ($< 1/10\ 000$) and not known (cannot be estimated from the available data).

Table 1: List of adverse reactions

System Organ Class	Frequency	Adverse reaction
Infections and infestations	Common	Fungal infections ^a
	Uncommon	Diverticulitis

^a Fungal infections include tinea pedis (n=4), tinea versicolor (n=2), oral candidiasis (n=2), onychomycosis (n=1), skin candida (n=1), urinary tract candidiasis (n=1), vulvovaginal candidiasis (n=1), fungal skin infection (n=1), genital infection fungal (n=1), ear infection fungal (n=1), and laryngitis fungal (n=1).

Paediatric patients

A total of 72 paediatric patients 12 to less than 18 years of age have been treated with icotrokinra 200 mg orally once daily in two clinical studies in moderate to severe plaque psoriasis. Of these, 71 patients were exposed to icotrokinra for at least 6 months and 67 patients were exposed to icotrokinra for at least one year. The safety profile in adolescents was consistent with the safety profile observed in the overall study population.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in [Appendix V](#).

4.9 Overdose

In clinical studies, single oral icotrokinra doses up to 1 000 mg have been administered to healthy subjects without adverse reactions.

There is no specific treatment in the event of an overdose. In the event of an overdose, administer appropriate symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Immunosuppressants, interleukin inhibitors, ATC code: L04AC28.

Mechanism of action

Icotrokinra is a peptide that binds selectively to the IL-23 receptor (IL-23R) with high affinity and competitively antagonizes the binding of IL-23. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses, but when produced in excess contributes to chronic

inflammation associated with plaque psoriasis. Icotrokinra inhibits the IL-23/IL-23R-dependent release of proinflammatory cytokines.

Pharmacodynamic effects

In evaluated patients with plaque psoriasis serum levels of IL-17A, IL-17F, IL-22, β -defensin-2 and IL-19 were reduced after treatment with icotrokinra. Gene expression levels of *IL-17A*, *IL-17F*, *IL-22*, *DEFB4A* and *IL-19* in psoriatic skin, were normalised to non-lesional skin. Reductions in epidermal thickness and densities of T cells, including CD8⁺ tissue resident memory T cells, were also observed.

Immunogenicity

Consistent with the potential immunogenic properties of medicinal products containing proteins or peptides, patients may develop antibodies following treatment with icotrokinra.

In four Phase III clinical studies through Week 52, 12.2% (291/2 387) of patients treated with icotrokinra developed antibodies to icotrokinra. Of these patients who developed antibodies to icotrokinra, none had antibodies that were classified as neutralizing antibodies.

In two Phase III clinical studies (ICONIC-LEAD and ICONIC-TOTAL) through Week 52, 32.4% (23/71) of adolescent patients treated with icotrokinra developed antibodies to icotrokinra.

There was no identified clinically significant effect of anti-drug antibodies on pharmacokinetics, safety or effectiveness of icotrokinra through Week 52.

Clinical efficacy

Plaque psoriasis

The efficacy of icotrokinra 200 mg orally once daily was evaluated in 2 492 patients (2 420 adult patients and 72 adolescent patients 12 years to less than 18 years of age and weighing at least 40 kg) with plaque psoriasis who were eligible for systemic therapy or phototherapy in four Phase III randomised, multi-centre, double-blind, placebo and/or active comparator-controlled studies ICONIC-LEAD, ICONIC-TOTAL, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2.

Adult and adolescent patients with moderate to severe plaque psoriasis

ICONIC-LEAD enrolled 684 patients (618 adult and 66 adolescent patients 12 years of age and older) with moderate to severe plaque psoriasis. Patients were randomised to either icotrokinra 200 mg orally once daily or placebo for 16 weeks.

ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2 evaluated 1 497 adult patients with moderate to severe plaque psoriasis. Patients were randomised to either icotrokinra 200 mg orally once daily, deucravacitinib 6 mg orally once daily or placebo.

In these three studies moderate to severe plaque psoriasis was defined as IGA score (Investigator's Global Assessment) ≥ 3 , PASI score (Psoriasis Area and Severity Index) ≥ 12 and BSA (body surface area involvement) $\geq 10\%$.

Across the three studies, 67% of patients were male and 76% of the patients were White. The mean age was 45 (range: 12 to 86) years, the mean baseline weight was 88 (range: 39 to 211) kg for adults and was 73 (range: 41 to 130) kg for adolescents, 3% were 12 years to less than 18 years of age and 10% were ≥ 65 years. At baseline, the patients had a median affected BSA of 20.5%, a median PASI score of 18, and 14% of adults and 4.5% of adolescents had a history of psoriatic arthritis. The proportions of patients with a baseline IGA score of 3 [moderate] and 4 [severe] were 78% and 22%, respectively. At baseline, 72% had prior systemic treatment, 32% of patients had received prior

phototherapy, and 28% had received prior biologic therapy (anti-TNF agents: 13%, IL-12/23 inhibitors: 8%, IL-23 inhibitors: 9% and IL-17 inhibitors: 9%).

The efficacy of icotrokinra was evaluated with respect to overall skin disease, specific body locations (scalp, genitalia, nails, and hand/foot), patient reported outcomes and impact on quality of life. The co-primary endpoints were the proportion of patients who achieved (1) an IGA cleared or minimal (IGA 0/1) with at least two grade improvement from baseline and (2) PASI 90 response at Week 16 versus placebo. Main clinical outcomes are presented in Table 2.

Table 2: Summary of clinical responses in adult and adolescent patients with moderate to severe plaque psoriasis

Endpoint	ICONIC-LEAD		ICONIC-ADVANCE 1			ICONIC-ADVANCE 2		
	Icotrokinra (N=456) n (%)	Placebo (N=228) n (%)	Icotrokinra (N=311) n (%)	Deucravacitinib (N=307) n (%)	Placebo (N=156) n (%)	Icotrokinra (N=320) n (%)	Deucravacitinib (N=322) n (%)	Placebo (N=81) n (%)
Co-primary endpoints^a								
IGA 0 or 1 and a ≥2-grade improvement from baseline								
Week 16	295 (65%)	19 (8%)	213 (68%)	154 (50%) ^c	17 (11%)	227 (71%)	177 (55%) ^c	7 (9%)
Difference from placebo, % (95% CI)	--	56% (50%, 62%) ^b	--	--	58% (50%, 64%) ^b	--	--	63% (53%, 70%) ^b
Week 24	--	--	230 (74%)	161 (52%) ^c	--	220 (69%)	179 (56%) ^c	--
PASI 90								
Week 16	226 (50%)	10 (4.4%)	171 (55%)	91 (30%) ^c	6 (3.8%)	184 (58%)	111 (34%) ^c	1 (1.2%)
Difference from placebo, % (95% CI)	--	45% (40%, 50%) ^b	--	--	51% (44%, 57%) ^b	--	--	57% (49%, 62%) ^b
Week 24	--	--	205 (66%)	127 (41%) ^c	--	208 (65%)	141 (44%) ^c	--
Key secondary endpoints								
IGA 0								
Week 16	152 (33%)	3 (1.3%) ^b	114 (37%)	48 (16%) ^c	3 (1.9%) ^b	118 (37%)	57 (18%) ^c	1 (1.2%) ^b
Week 24	--	--	150 (48%)	63 (21%) ^c	--	128 (40%)	68 (21%) ^c	--
PASI 100								
Week 16	123 (27%)	1 (0.4%) ^b	97 (31%)	34 (11%) ^c	2 (1.3%) ^b	102 (32%)	46 (14%) ^c	1 (1.2%) ^b
Week 24	--	--	129 (41%)	49 (16%) ^c	--	107 (33%)	52 (16%) ^c	--
ss-IGA 0/1 (scalp) and a ≥2-grade improvement from baseline								
N ^d	405	200	261		134	268		70
Week 16	293 (72%)	30 (15%) ^b	189 (72%)		28 (21%) ^b	199 (74%)		13 (19%) ^b

IGA = Investigator's Global Assessment; CI = Confidence interval; ss-IGA = scalp-specific Investigator's Global Assessment; PASI = Psoriasis Area and Severity Index

^a Co-primary endpoints comparing icotrokinra to placebo at Week 16. Key secondary endpoints comparing icotrokinra to deucravacitinib at Week 16 and Week 24.

^b $p < 0.001$ for comparison between icotrokinra and placebo, adjusted for multiplicity.

^c $p < 0.001$ for comparison between icotrokinra and deucravacitinib, adjusted for multiplicity.

^d Includes patients with baseline ss-IGA score ≥ 2 .

In ICONIC-LEAD, a significantly greater proportion of patients randomised to icotrokinra achieved PASI 75 at Week 4 compared to placebo (14.9% vs 2.2% respectively, p -value < 0.002) and PASI 90 at Week 8 compared to placebo (21% vs 1.3% respectively, p -value < 0.001). Similar response was observed in ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2.

Maintenance and durability of response through Week 52 (ICONIC-LEAD)

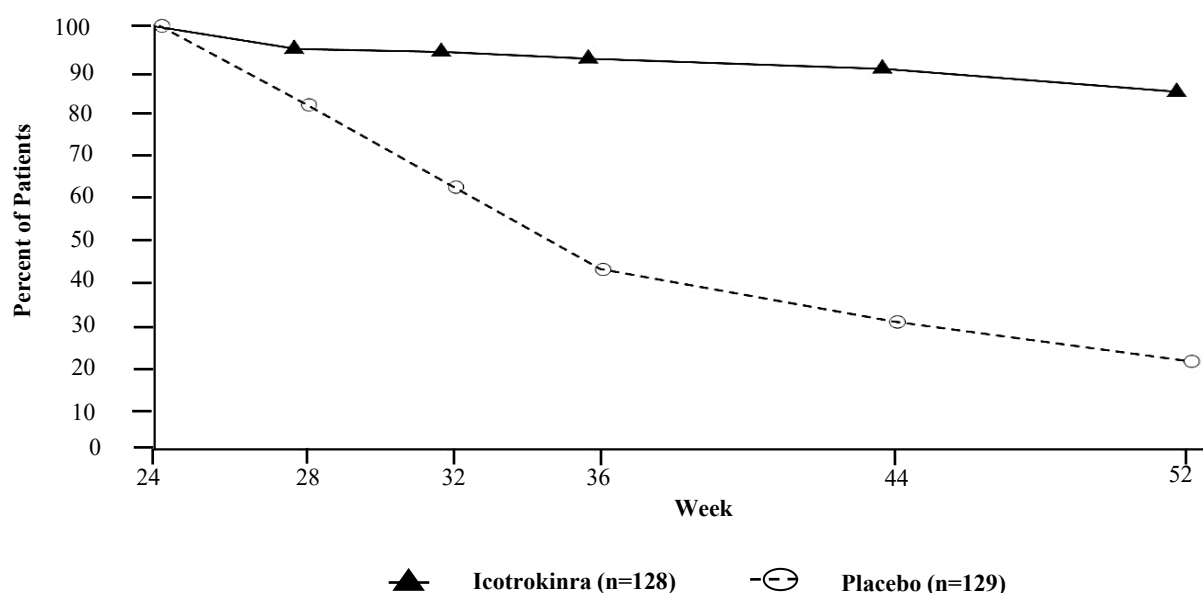
Adult patients who were randomised to icotrokinra 200 mg orally once daily at baseline and were PASI 75 responders or IGA 0 or 1 responders at Week 24 were re-randomised to either continue icotrokinra 200 mg or withdrawn from therapy (i.e. received placebo) and were followed until Week 52.

Among adult patients who were re-randomised and had a PASI 90 response at Week 24, 84% (108/128) of patients who continued on icotrokinra maintained response at Week 52 compared to 21%

(27/129) of patients randomised to placebo. The median time to loss of PASI 75 response was 16 weeks and of PASI 90 response was approximately 10 weeks in those re-randomised to placebo.

Figure 1 presents the percentage of patients maintaining PASI 90 response through Week 52 after re-randomisation at Week 24 in ICONIC-LEAD.

Figure 1: PASI 90 response rate in adults patients who were PASI 90 responders at Week 24 after re-randomisation at Week 24 in ICONIC-LEAD



Response over time through Week 52

Icotrokinra showed early onset of efficacy in adult patients with IGA 0/1 responses with a ≥ 2 -grade improvement from baseline, observed as early as Week 4, with continued improvement through Week 24 and maintained through Week 52 in ICONIC-ADVANCE 1 (see Figure 2).

Similar responses through Week 52 were seen in ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2.

Figure 2: Proportion of adult patients with moderate to severe plaque psoriasis with IGA 0/1 response with a ≥ 2 -grade improvement from baseline through Week 52 (ICONIC-ADVANCE 1)

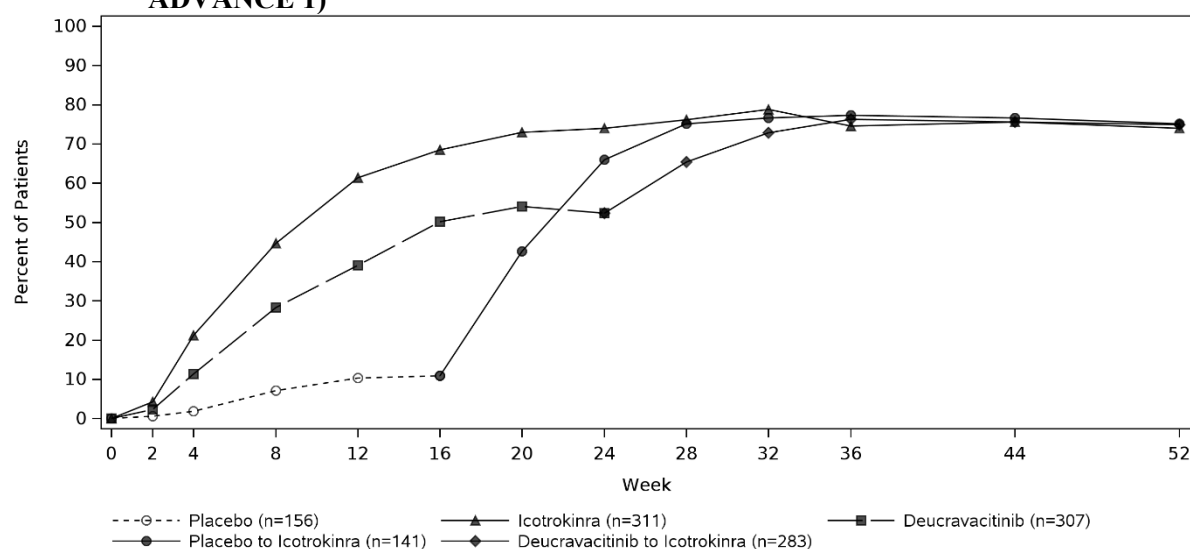


Table 3: Summary of patient reported outcomes in adult patients with moderate to severe plaque psoriasis (ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2)

Endpoint	ICONIC-ADVANCE 1			ICONIC-ADVANCE 2		
	Icotrekinra (N=311) n (%)	Deucravacitinib (N=307) n (%)	Placebo (N=156) n (%)	Icotrekinra (N=320) n (%)	Deucravacitinib (N=322) n (%)	Placebo (N=81) n (%)
PSSD symptom score 0						
N ^a	286	272	142	296	282	70
Week 8	24 (8%)	--	3 (2.1%) ^b	27 (9%)	--	1 (1.4%) ^c
Week 16	68 (24%)	25 (9%) ^d	4 (2.8%) ^e	64 (22%)	36 (13%) ^f	0 ^e
PSSD itch NRS (≥4-point improvement)						
N ^g	251	236	115	256	242	60
Week 4	56 (22%)	--	8 (7%) ^e	54 (21%)	--	3 (4.9%) ^h
Week 16	155 (62%)	127 (54%) ⁱ	19 (17%) ^e	154 (60%)	125 (52%) ⁱ	9 (15%) ^e
DLQI score 0/1						
N ^j	304	294	149	317	318	80
Week 16	172 (57%)	121 (41%) ⁱ	17 (11%) ⁱ	168 (53%)	127 (40%) ⁱ	11 (14%) ⁱ

PSSD = Psoriasis Symptoms and Signs Diary; DLQI = Dermatology Life Quality Index; NRS = Numeric Rating Scale

^a Includes patients with baseline PSSD Symptom Score > 0.

^b p = 0.011 for comparison between icotrekinra and placebo, adjusted for multiplicity.

^c p = 0.025 for comparison between icotrekinra and placebo, adjusted for multiplicity.

^d p < 0.001 for comparison between icotrekinra and deucravacitinib, adjusted for multiplicity.

^e p < 0.001 for comparison between icotrekinra and placebo, adjusted for multiplicity.

^f p = 0.005 for comparison between icotrekinra and deucravacitinib, adjusted for multiplicity.

^g Includes patients with baseline PSSD Itch Score ≥ 4.

^h p = 0.008 for comparison between icotrekinra and placebo, adjusted for multiplicity.

ⁱ These endpoints were not multiplicity-controlled.

^j Includes patients with baseline DLQI score > 1.

At Week 16, patient reported outcomes results in ICONIC-LEAD in adults and adolescents were comparable to those observed in ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2.

Adults and adolescents with plaque psoriasis involving special areas (scalp, genitalia and hand/foot)

ICONIC-TOTAL enrolled adult and adolescent patients with plaque psoriasis who had failed to respond to at least one topical therapy for the treatment of plaque psoriasis. Additionally, patients needed to have at least moderate scalp, genital, or hand/foot psoriasis.

A total of 311 patients (305 adult and 6 adolescent patients) were randomised to either icotrekinra 200 mg orally once daily or placebo for 16 weeks; 64% were male, and 78% were White. The mean age was 45 (range: 12 to 87) years, the mean baseline weight was 86 (range: 40 to 246) kg, 1.9% were 12 years to less than 18 years of age, and 8% were ≥ 65 years. The proportion of patients with affected BSA 1% to less than 10% was 36% with a median affected BSA of 12%. The proportion of patients with a baseline IGA score of 2 [mild], 3 [moderate] and 4 [severe] were 5%, 73%, and 22%, respectively. The proportion of patients with a baseline scalp-specific Investigator's Global Assessment (ss-IGA) score of 3 or greater was 81%. The proportion of patients with Static Physician's Global Assessment of Genitalia (sPGA-G) score of 3 or greater was 45%. The proportion of patients with Physician's Global Assessment of Hands and Feet (hf-PGA) score of 3 or greater was 23%. Scalp, genital and hand/foot subpopulations are not mutually exclusive. At baseline, 73% had received prior systemic therapy, 39% of patients had received prior phototherapy and 33% had received prior biologic therapy (anti-TNF agents: 14%, IL-12/23 inhibitors: 9%, IL-23 inhibitors: 12% and IL-17 inhibitors: 9%).

The primary endpoint was the proportion of patients who achieved an IGA score of 0 or 1 and a ≥ 2-grade improvement from baseline at Week 16. Main clinical outcomes are presented in Table 4.

Table 4: Summary of efficacy results in adult (n=305) and adolescent (n=6) patients with plaque psoriasis involving special areas (scalp, genitalia and hand/foot) (ICONIC-TOTAL)

Endpoint	Icotrekinra (N=208) n (%)	Placebo (N=103) n (%)
Primary endpoint		
IGA 0 or 1 and a $\geq$ 2-grade improvement from baseline		
Week 16 ^a	118 (57%)	6 (6%)
Difference from placebo, % (95% CI)		51% (42%, 59%) ^b
Key secondary endpoints		
ss-IGA 0/1 (scalp)		
N ^c	167	85
Week 16	110 (66%)	9 (11%) ^b
Scalp itch ($\geq$ 4-point improvement)		
N ^d	131	58
Week 16	77 (59%)	5 (9%) ^e
sPGA-G 0/1 (genitalia)		
N ^f	98	42
Week 16	75 (77%)	9 (21%) ^b
GPSS genital itch ($\geq$ 4-point improvement)		
N ^g	69	31
Week 16	44 (64%)	4 (13%) ^e
GenPs-SFQ item 2 score 0/1 (genitalia)		
N ^h	55	25
Week 16	44 (80%)	9 (36%) ^e
hf-PGA 0/1 (hand/foot)		
N ⁱ	48	23
Week 16	20 (42%)	6 (26%) ^j

IGA = Investigator's Global Assessment; CI = Confidence Interval; ss-IGA = scalp-specific Investigator's Global Assessment; sPGA-G = Static Physician's Global Assessment of Genitalia; GPSS = Genital Psoriasis Symptoms Scale; GenPs-SFQ = Genital Psoriasis Sexual Frequency Questionnaire; hf-PGA = Physician's Global Assessment of Hands and Feet; NRS = Numeric Rating Scale

^a Primary endpoint comparing icotrekinra to placebo.

^b $p < 0.001$ for comparison between icotrekinra and placebo, adjusted for multiplicity.

^c Includes patients with baseline ss-IGA score ≥ 3 .

^d Includes patients with baseline Scalp Itch NRS Score ≥ 4 and baseline ss-IGA score ≥ 3 .

^e $p = 0.008$ for comparison between icotrekinra and placebo, adjusted for multiplicity.

^f Includes patients with baseline sPGA-G score ≥ 3 .

^g Includes patients with baseline GPSS Genital Itch NRS Score ≥ 4 and baseline sPGA-G score ≥ 3 .

^h Includes patients with baseline GenPs-SFQ Item 2 score ≥ 2 and baseline sPGA-G score ≥ 3 .

ⁱ Includes patients with baseline hf-PGA score ≥ 3 .

^j $p = 0.144$ for comparison between icotrekinra and placebo, adjusted for multiplicity (not significant).

In ICONIC-LEAD, greater improvement (reductions) in nail psoriasis, as measured by the mean percent change in Nail Psoriasis Severity Index (mNAPSI) from baseline, were observed in patients receiving icotrekinra compared to placebo-treated patients at Week 16 (icotrekinra: -37.9%; placebo: 1.7%). These effects were observed through Week 24.

Treatment with icotrekinra resulted in consistent improvements in patients with scalp, genital, hand/foot, nail psoriasis at baseline in studies ICONIC-LEAD, ICONIC-ADVANCE 1, and ICONIC-ADVANCE 2. These effects were observed through Week 24.

Paediatric population

The efficacy of icotrekinra was evaluated in 72 adolescents 12 years of age and older and weighing at least 40 kg.

In the ICONIC-LEAD study, 44% were male and, 73% were White. The mean age of adolescents was 15 (range: 12 to 17) years, and the mean weight was 73 (range 41 to 130) kg. Frequency of moderate and severe plaque psoriasis, median PASI and median affected BSA at baseline were comparable in

adolescents and adults. The adolescents had a median affected BSA of 23% and a median baseline PASI score of 18. In the ICONIC-LEAD study, the proportions of adolescents with scalp psoriasis (97%) or genital psoriasis (38%) at baseline were comparable with those of adults (94% and 37%, respectively). Higher proportion of adults, 47% had hand/feet psoriasis at baseline compared to adolescents (33%). At baseline, 52% of adolescents had received prior systemic therapy, 20% had received prior phototherapy, and 23% had received prior biologic therapy (anti-TNF agents: 12%, IL-12/23 inhibitors: 4.5%, IL-23 inhibitors: 1.5% and IL-17 inhibitors: 9%). Use of prior systemic therapy was less in adolescents compared to adults, as expected. The results in adolescents from ICONIC-LEAD are presented in Table 5 (endpoints not multiplicity-controlled).

Table 5: Summary of clinical responses and patient reported outcomes for adolescents with moderate to severe plaque psoriasis (ICONIC-LEAD)

Endpoint	Icotrekinra (N=44) n (%)	Placebo (N=22) n (%)
IGA 0 or 1 and a ≥ 2-grade improvement from baseline		
Week 16	37 (84%)	6 (27%)
IGA 0		
Week 16	18 (41%)	1 (4.5%)
PASI 90		
Week 16	31 (70%)	3 (14%)
PASI 100		
Week 16	13 (30%)	1 (4.5%)
CDLQI score 0/1^a		
N	40	19
Week 16	27 (68%)	2 (11%)

IGA = Investigator's Global Assessment; PASI = Psoriasis Area and Severity Index; CDLQI = Children's Dermatology Life Quality Index

^a Includes patients with baseline CDLQI score > 1.

Note: These endpoints included were not multiplicity-controlled.

Short-term response rates in adolescents in ICONIC-LEAD at Week 16 were comparable to those in the adult population. The adolescent cohort did not participate in the randomised withdrawal phase. Open-label data support clinically relevant benefit in adolescents with continued treatment with icotrekinra through Week 52. Comparative Week 52 across study data support similar long-term response rates in adolescents and adults.

In ICONIC-TOTAL, only 6 adolescents were included. A numerically greater proportion of adolescents 12 years of age and older treated with icotrekinra compared to placebo achieved an IGA score of 0 or 1 and a ≥ 2 grade improvement from baseline at Week 16 (67% in icotrekinra [N=3] vs. 0 in placebo [N=3]). From Week 16 through Week 52, treatment both in adults and adolescents was open-label and uncontrolled.

The European Medicines Agency has deferred the obligation to submit the results of studies with ICOTYDE in one or more subsets of the paediatric population in the treatment of plaque psoriasis (see section 4.2 for information on paediatric use).

5.2 Pharmacokinetic properties

Absorption

Icotrekinra is a compound with low solubility and low permeability.

The median (range) T_{max} of icotrekinra after oral administration is 2.00 (0.25-8.00) hours in healthy subjects. The mean C_{max} and mean AUC_{∞} of icotrekinra were 3.62 ng/mL and 44.8 ng.h/mL, respectively.

After repeat once daily dosing of icotrekinra, steady-state icotrekinra is expected within 3 days with minimal accumulation, consistent with its terminal half-life.

Inter-subject variability of $C_{\max}$ and AUC_{∞} was estimated to be 26.7% and 19.6%, respectively. Intra-subject variability of $C_{\max}$ and AUC_{∞} was estimated to be 35.6% and 20.7%, respectively.

Based on nonclinical data, the absolute bioavailability of icotrokinra was $< 1\%$.

Food effect

In healthy subjects, co-administration of a single icotrokinra 200 mg dose orally with a high-calorie, high-fat meal decreased icotrokinra AUC_{∞} and $C_{\max}$ by 43% and 59%, respectively, relative to fasted state. Icotrokinra should be taken upon waking at least 30 minutes before eating food.

Oral administration of a single icotrokinra 200 mg tablet with caffeine resulted in no difference in exposure.

Co-administration of a single icotrokinra 200 mg tablet orally with whole milk decreased $C_{\max}$ by 33% and AUC_{∞} by 24% compared with co-administration with water.

Distribution

Icotrokinra is 52% bound to plasma protein. Blood to plasma partition ratio was 0.53. The volume of distribution (V/F) at steady state is 92 800 L.

Biotransformation

Icotrokinra is a peptide, and intact active substance is the main medicine-related species in plasma. Icotrokinra is metabolised by peptide catabolism into smaller peptides and is not metabolised by CYP enzymes.

Elimination

The median terminal half-life ($t_{1/2}$) of icotrokinra is 12 hours. Clearance following oral dosing (Cl/F) is 6 550 L/h.

The majority of the active substance is not absorbed with 37% to 81% of the intact medicine recovered unchanged in faeces up to 24 hours after oral dosing of 10 to 1 000 mg. Less than 0.001% of administered dose was recovered as intact medicine in urine.

Renal clearance is the main route of elimination for the absorbed medicine.

Linearity

Following oral administration, icotrokinra $C_{\max}$ and AUC increased in an almost dose-proportional manner over a dose range of 10 to 1 000 mg (approximately 0.05 to 5 times the recommended dose) in healthy subjects.

Immunogenicity

Among icotrokinra-treated patients who developed anti-drug antibodies, population pharmacokinetic analysis using pooled data from the four Phase III clinical studies through Week 52 showed that $C_{\max}$ and AUC increased by 1.2- and 1.3-fold respectively, compared with patients who did not develop anti-drug antibodies.

There was no identified clinically significant effect of anti-drug antibodies on pharmacokinetics, safety or effectiveness of icotrokinra through Week 52.

Special populations

Based on population pharmacokinetic analysis, age (12-87 years), sex, race, ethnicity, do not have a clinically meaningful effect on the pharmacokinetics of icotrokinra.

Body weight

Clearance and volume of distribution of icotrokinra after oral dosing increased with increasing body weight (39-211 kg). These differences are not clinically meaningful, and no dose adjustment is warranted.

Paediatric population (12 years to less than 18 years of age)

No meaningful difference in the systemic exposure of icotrokinra was observed in paediatric patients with plaque psoriasis 12 years of age and older weighing at least 40 kg compared to adults.

Elderly

In the population pharmacokinetic analysis, age did not have a significant impact on the pharmacokinetics of icotrokinra.

Renal impairment

Icotrokinra AUC_{∞} increased 2.47-fold and 2.78-fold in patients with moderate renal impairment ($eGFR \geq 30$ to < 60 mL/min) and severe renal impairment ($eGFR \geq 15$ to < 30 mL/min), respectively, compared to patients with normal renal function ($eGFR \geq 90$ mL/min). Mild renal impairment ($eGFR \geq 60$ to < 90 mL/min) had no effect on icotrokinra exposure based on population pharmacokinetic analysis. Patients with end-stage renal disease ($eGFR < 15$ mL/min) or patients on dialysis were not studied (see section 4.2).

Icotrokinra C_{max} increased 1.79-fold and 1.27-fold in patients with moderate renal impairment ($eGFR \geq 30$ to < 60 mL/min) and severe renal impairment ($eGFR \geq 15$ to < 30 mL/min), respectively, compared to patients with normal renal function ($eGFR \geq 90$ mL/min).

Hepatic impairment

No formal pharmacokinetic studies with icotrokinra were conducted in patients with hepatic impairment. Changes in hepatic function are unlikely to have any effect on the elimination of icotrokinra as icotrokinra is not metabolised through hepatic pathways.

5.3 Preclinical safety data

Nonclinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenicity, and toxicity to reproduction and development.

Icotrokinra was neither embryo-lethal nor teratogenic in rats or rabbits at maternal exposures at least 95 times the maximum recommended human dose (MRHD), respectively based on unbound AUC. In rabbits, maternal body weight loss, low food consumption, and pregnancy losses were observed at maternal exposures 95 times the MRHD based on unbound AUC.

Icotrokinra had no effects on prenatal and post-natal development in rats at maternal exposures 127 times the MRHD based on total AUC. Although not directly measured in rat milk, icotrokinra was detected in the plasma of nursing rat pups. On post-natal day 12, the mean pup-to-maternal plasma ratio for icotrokinra was 0.042 to 0.29.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core

Crospovidone (E1202)
Magnesium stearate (E572)
Silica colloidal anhydrous (E551)
Silicified microcrystalline cellulose (silica colloidal, anhydrous and microcrystalline cellulose)

Film-coating

Glycerol Monocaprylocaprate Type 1 (E471)
Iron oxide yellow (E172)
Macrogol Polyvinyl Alcohol, Graft Copolymer (E1209)
Polyvinyl alcohol partially hydrolysed (E1203)
Talc (E553b)
Titanium dioxide (E171)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.

Blister

Store in the original package in order to protect from moisture.

Bottle

Store in the original package and keep the bottle tightly closed in order to protect from moisture.

6.5 Nature and contents of container

Blister

Film-coated tablets are packaged in aluminium/aluminium foil perforated unit dose blisters.

- Unit packs containing 7 x 1 film-coated tablets (1 blister strip of 7 tablets) or 28 x 1 film-coated tablets (4 blister strips of 7 tablets each).
- Multipacks containing 84 (3 packs of 28 x 1) film-coated tablets.

Bottle

HDPE bottle with a silica gel desiccant and a child resistant polypropylene closure containing 30 film-coated tablets. Patients should be instructed to keep the desiccant in the bottle and not to swallow it.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/26/2063/001
EU/1/26/2063/002
EU/1/26/2063/003
EU/1/26/2063/004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency <https://www.ema.europa.eu>

ANNEX II

- A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**
- D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Janssen Cilag SpA
Via C. Janssen
Borgo San Michele
04100 Latina
Italy

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic safety update reports (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

The marketing authorisation holder (MAH) shall submit the first PSUR for this product within 6 months following authorisation.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk management plan (RMP)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON - UNIT PACK BLISTER****1. NAME OF THE MEDICINAL PRODUCT**

ICOTYDE 200 mg film-coated tablets
icotrokinra

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains icotrokinra hydrochloride equivalent to 200 mg icotrokinra.

3. LIST OF EXCIPIENTS**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablets

7 x 1 film-coated tablets

28 x 1 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/26/2063/001 7 x 1 film-coated tablets
EU/1/26/2063/002 28 x 1 film-coated tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

icotyde 200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER LABEL - MULTIPACK BLISTER (WITH BLUE BOX)

1. NAME OF THE MEDICINAL PRODUCT

ICOTYDE 200 mg film-coated tablets
icotrokinra

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains icotrokinra hydrochloride equivalent to 200 mg icotrokinra.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets

Multipack: 84 (3 packs of 28 x 1) film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/26/2063/003 84 (3 packs of 28 x 1) film-coated tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

icotyde 200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**INTERMEDIATE CARTON - MULTIPACK BLISTER (WITHOUT BLUE BOX)****1. NAME OF THE MEDICINAL PRODUCT**

ICOTYDE 200 mg film-coated tablets
icotrokinra

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains icotrokinra hydrochloride equivalent to 200 mg icotrokinra.

3. LIST OF EXCIPIENTS**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablets

28 x 1 film-coated tablets. Component of a multipack, can't be sold separately.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/26/2063/003 84 (3 packs of 28 x 1) film-coated tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

icotyde 200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS
--

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

ICOTYDE 200 mg tablets
icotrokinra

2. NAME OF THE MARKETING AUTHORISATION HOLDER
--

Janssen-Cilag Int

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

Day 1
Day 2
Day 3
Day 4
Day 5
Day 6
Day 7

PARTICULARS TO APPEAR ON THE OUTER PACKAGING**OUTER CARTON - BOTTLE****1. NAME OF THE MEDICINAL PRODUCT**

ICOTYDE 200 mg film-coated tablets
icotrokinra

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains icotrokinra hydrochloride equivalent to 200 mg icotrokinra.

3. LIST OF EXCIPIENTS**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablets

30 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package and keep the bottle tightly closed in order to protect from moisture. Do not swallow or remove the desiccant.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/26/2063/004

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

icotyde 200 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC
SN
NN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING**BOTTLE LABEL****1. NAME OF THE MEDICINAL PRODUCT**

ICOTYDE 200 mg film-coated tablets
icotrokinra

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains icotrokinra hydrochloride equivalent to 200 mg icotrokinra.

3. LIST OF EXCIPIENTS**4. PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablets

30 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package and keep the bottle tightly closed in order to protect from moisture. Do not swallow or remove the desiccant.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Janssen-Cilag International NV

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/26/2063/004

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

ICOTYDE 200 mg film-coated tablet icotrokinra

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ICOTYDE is and what it is used for
2. What you need to know before you take ICOTYDE
3. How to take ICOTYDE
4. Possible side effects
5. How to store ICOTYDE
6. Contents of the pack and other information

1. What ICOTYDE is and what it is used for

What ICOTYDE is

ICOTYDE contains the active substance icotrokinra.

This medicine helps to control the inflammation associated with psoriasis by blocking a protein called IL-23R, which is increased in people with psoriasis.

ICOTYDE is used to treat moderate-to-severe plaque psoriasis (a disease causing red, scaly patches on the skin). It is used in adults, and adolescents aged 12 years and older with a body weight of at least 40 kg.

ICOTYDE can improve the condition of the skin and appearance of nails. ICOTYDE can reduce signs such as scaling, redness and skin thickness and improve symptoms such as itching, pain, stinging, burning and skin tightness. ICOTYDE can also improve the quality of life in patients with psoriasis.

2. What you need to know before you take ICOTYDE

Do not take ICOTYDE

- if you are allergic to icotrokinra or any of the other ingredients of this medicine (listed in section 6).
- if you have an active infection, including active tuberculosis, which your doctor thinks is important.

Warnings and precautions

Talk to your doctor or pharmacist before and during the use of ICOTYDE:

- if you have recently received or are scheduled to receive an immunisation (vaccine):

- you should avoid receiving live vaccines during treatment with ICOTYDE and within 3 days after stopping treatment with ICOTYDE.
- if you currently have an infection, a long-term infection, or if you have an infection that keeps coming back.

Children and adolescents

ICOTYDE is not recommended for children and adolescents under 12 years of age or with a body weight below 40 kg because it has not been studied in this group.

Other medicines and ICOTYDE

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This is because it is not known how this medicine will affect the unborn baby.

If you took ICOTYDE when you were pregnant:

- tell your baby's doctor and other health care professionals before your baby has any vaccines.
- live vaccines are not recommended for your baby in the first 3 days after birth unless your baby's doctor recommends otherwise.

It is unknown whether ICOTYDE passes into human breast milk. Talk to your doctor if you are breast-feeding or are planning to breast-feed. You and your doctor should decide if you will breast-feed or use ICOTYDE.

Driving and using machines

ICOTYDE is unlikely to influence your ability to drive and use machines.

3. How to take ICOTYDE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

ICOTYDE is available as a tablet which is taken by mouth.

The recommended dose is 200 mg every day.

- Take on an empty stomach after you wake up.
- Swallow the tablet whole with water.
- After taking the ICOTYDE tablet, wait at least 30 minutes before eating food.

If you have trouble swallowing whole tablets

- Place one tablet in a cup with at least 120 mL of water.
- Wait a few minutes until the tablet breaks up and spreads out. The mixture may look yellow, milky, or cloudy. Small pieces may be seen in the water – these are safe to swallow.
- Swirl the mixture in the cup before drinking and swallow the full mixture straight away.
- Fill the cup with at least another 120 mL of water and drink straight away to make sure that you take the full dose.

If you take more ICOTYDE than you should

If you take more ICOTYDE than you should, talk to your doctor straight away.

If you forget to take ICOTYDE

If you forget to take a dose, take the missed dose on the same day as soon as possible. Take your next dose at the usual time on the next day.

Do not take a double dose to make up for a forgotten dose.

If you stop taking ICOTYDE

Do not stop using this medicine without talking to your doctor. If you stop treatment, symptoms of psoriasis may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor, pharmacist or nurse if you get any of the following side effects

Common (may affect up to 1 in 10 people)

- fungal infection

Uncommon (may affect up to 1 in 100 people)

- inflamed lower part of the gut (diverticulitis)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ICOTYDE

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister, bottle and carton after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.

Blister: Store in the original package in order to protect from moisture.

Bottle: Store in the original package and keep the bottle tightly closed in order to protect from moisture.

Do not use this medicine if you notice the tablets are damaged or there are signs of tampering with the medicine packaging.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ICOTYDE contains

- The active substance is icotrokinra. Each film-coated tablet contains 200 mg of icotrokinra.
- The other ingredients are:

- Tablet core: colloidal anhydrous silica (E551), crospovidone (E1202), magnesium stearate (E572), silicified microcrystalline cellulose.
- Film-coating: macrogol polyvinyl alcohol graft copolymer (E1209), talc (E553b), titanium dioxide (E171), glycerol monocaprylocaprate (E471), polyvinyl alcohol partially hydrolysed (E1203) and iron oxide yellow (E172).

What ICOTYDE looks like and contents of the pack

ICOTYDE is a yellowish orange to yellowish brown, oval film-coated tablet (tablet) approximately 19 mm in length and 9 mm in width debossed with '200' on one side and 'JNJ' on the other side.

The tablets may be supplied either in a bottle or in a blister pack.

Blister

ICOTYDE 200 mg film-coated tablets are available in the following packs:

- Unit packs containing 7 x 1 film-coated tablets in 1 aluminum perforated unit dose blister card OR
- Unit packs containing 28 x 1 film-coated tablets in 4 aluminum perforated unit dose blister cards of 7 tablets each OR
- Multipacks containing 84 (3 packs of 28 x 1) film-coated tablets

Bottle

The film-coated tablets are supplied in a plastic bottle with a child-resistant closure. Each bottle contains 30 film-coated tablets and a desiccant. Each carton contains one bottle. Do not swallow or remove the desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Janssen-Cilag International NV
Turnhoutseweg 30
B-2340 Beerse
Belgium

Manufacturer

Janssen Cilag SpA
Via C. Janssen
Borgo San Michele
04100 Latina
Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Κύπρος

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<https://www.ema.europa.eu>