

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SOMAC Control 20 mg gastro-resistant tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant tablet contains 20 mg pantoprazole (as sodium sesquihydrate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gastro-resistant tablet.

Yellow, oval, biconvex film-coated tablets imprinted with “P20” in brown ink on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SOMAC Control is indicated for short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.

4.2 Posology and method of administration

Posology

The recommended dose is 20 mg pantoprazole (one tablet) per day.

It might be necessary to take the tablets for 2-3 consecutive days to achieve improvement of symptoms. Once complete relief of symptoms has occurred, treatment should be discontinued.

The treatment should not exceed 4 weeks without consulting a doctor.

If no symptom relief is obtained within 2 weeks of continuous treatment, the patient should be instructed to consult a doctor.

Special populations

No dose adjustment is necessary in elderly patients or in those with impaired renal or liver function.

Paediatric population

SOMAC Control is not recommended for use in children and adolescents below 18 years of age due to insufficient data on safety and efficacy.

Method of administration

SOMAC Control 20 mg gastro-resistant tablets should not be chewed or crushed, and should be swallowed whole with liquid before a meal.

4.3 Contraindications

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

Co-administration of pantoprazole is not recommended with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir, nelfinavir; due to significant reduction in their bioavailability (see section 4.5).

4.4 Special warnings and precautions for use

Patients should be instructed to consult a doctor if:

- They have unintentional weight loss, anaemia, gastrointestinal bleeding, dysphagia, persistent vomiting or vomiting with blood, since pantoprazole may alleviate symptoms and delay diagnosis of a severe condition. In these cases, malignancy should be excluded.
- They have had previous gastric ulcer or gastrointestinal surgery.
- They are on continuous symptomatic treatment of indigestion or heartburn for 4 or more weeks.
- They have jaundice, hepatic impairment, or liver disease.
- They have any other serious disease affecting general well-being.
- They are aged over 55 years with new or recently changed symptoms.

Patients with long-term recurrent symptoms of indigestion or heartburn should see their doctor at regular intervals. Especially, patients over 55 years taking any non-prescription indigestion or heartburn remedy on a daily basis should inform their pharmacist or doctor.

Patients should not take another proton pump inhibitor or H₂ antagonist concomitantly.

Patients should consult their doctor before taking this medicinal product if they are due to have an endoscopy or urea breath test.

Patients should be advised that the tablets are not intended to provide immediate relief.

Patients may start to experience symptomatic relief after approximately one day of treatment with pantoprazole, but it might be necessary to take it for 7 days to achieve complete heartburn control. Patients should not take pantoprazole as a preventive medicinal product.

Gastrointestinal infections caused by bacteria

Decreased gastric acidity, due to any means - including proton pump inhibitors - increases gastric counts of bacteria normally present in the gastrointestinal tract. Treatment with acid-reducing medicinal products leads to a slightly increased risk of gastrointestinal infections such as *Salmonella*, *Campylobacter*, or *Clostridium difficile*.

Severe cutaneous adverse reactions (SCARs)

Severe cutaneous adverse reactions (SCARs) including erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) which can be life-threatening or fatal, have been reported in association with pantoprazole with frequency not known (see section 4.8).

Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, pantoprazole should be withdrawn immediately and an alternative treatment considered.

Subacute cutaneous lupus erythematosus (SCLE)

Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping SOMAC Control. SCLE after

previous treatment with a proton pump inhibitor may increase the risk of SCLÉ with other proton pump inhibitors.

Interference with laboratory tests

Increased Chromogranin A (CgA) level may interfere with investigations for neuroendocrine tumours. To avoid this interference, SOMAC Control treatment should be stopped for at least 5 days before CgA measurements (see section 5.1). If CgA and gastrin levels have not returned to reference range after initial measurement, measurements should be repeated 14 days after cessation of proton pump inhibitor treatment.

The following additional risks are considered relevant for long-term use:

This medicinal product is intended for short-term use (up to 4 weeks) only (Refer to section 4.2). Patients should be warned about additional risks with long-term use of the medicinal products and the need for prescription and regular surveillance should be emphasised.

Influence on vitamin B₁₂ absorption

Pantoprazole, as all acid-blocking medicines, may reduce the absorption of vitamin B₁₂ (cyanocobalamin) due to hypo- or achlorhydria. This should be considered in patients with reduced body stores or risk factors for reduced vitamin B₁₂ absorption on long-term therapy or if respective clinical symptoms are observed.

Bone fracture

Proton pump inhibitors, especially if used in high doses and over long durations (> 1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in the presence of other recognised risk factors. Observational studies suggest that proton pump inhibitors may increase the overall risk of fracture by 10–40%. Some of this increase may be due to other risk factors. Patients at risk of osteoporosis should receive care according to current clinical guidelines and they should have an adequate intake of vitamin D and calcium.

Hypomagnesaemia

Severe hypomagnesaemia has been rarely reported in patients treated with proton pump inhibitors (PPIs) like pantoprazole for at least three months, and in most cases for a year. Serious manifestations of hypomagnesaemia such as fatigue, tetany, delirium, convulsions, dizziness, and ventricular arrhythmia can occur, but they may begin insidiously and be overlooked. Hypomagnesaemia may lead to hypocalcaemia and/or hypokalaemia (see section 4.8). In most affected patients, hypomagnesaemia (and hypomagnesaemia associated hypocalcaemia and/or hypokalaemia) improved after magnesium replacement and discontinuation of the PPI.

For patients expected to be on prolonged treatment or who take PPIs with digoxin or medicinal products that may cause hypomagnesaemia (e.g., diuretics), health care professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.

SOMAC Control contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Medicinal products with pH-dependent absorption pharmacokinetics

SOMAC Control may reduce the absorption of active substances whose bioavailability is dependent on the gastric pH (e.g., ketoconazole).

HIV protease inhibitors

Co-administration of pantoprazole is contraindicated with HIV protease inhibitors for which absorption is dependent on acidic intragastric pH such as atazanavir, nelfinavir; due to significant reduction in their bioavailability (see section 4.3).

Coumarin anticoagulants (phenprocoumon or warfarin)

Although no interaction during concomitant administration of phenprocoumon or warfarin has been observed in clinical pharmacokinetic studies, a few isolated cases of changes in International Normalised Ratio (INR) have been reported during concomitant treatment in the post-marketing period. Therefore, in patients treated with coumarin anticoagulants (e.g., phenprocoumon or warfarin), monitoring of prothrombin time/INR is recommended after initiation, termination or during irregular use of pantoprazole.

Methotrexate

Concomitant use of high-dose methotrexate (e.g., 300 mg) and proton pump inhibitors has been reported to increase methotrexate levels in some patients. Therefore, in settings where high-dose methotrexate is used, for example cancer and psoriasis, a temporary withdrawal of pantoprazole may need to be considered.

Other interactions studies

Pantoprazole is metabolised in the liver via the cytochrome P450 enzyme system. Interaction studies with carbamazepine, caffeine, diazepam, diclofenac, digoxin, ethanol, glibenclamide, metoprolol, naproxen, nifedipine, phenytoin, piroxicam, theophylline and an oral contraceptive containing levonorgestrel and ethinyl oestradiol did not reveal clinically significant interactions. However, an interaction of pantoprazole with other substances which are metabolised by the same enzyme system cannot be excluded.

There were no interactions with concomitantly administered antacids.

Drug-laboratory test interactions

There have been reports of false-positive results in some urine screening tests for tetrahydrocannabinol (THC) in patients receiving pantoprazole. An alternative confirmatory method should be considered to verify positive results.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of pantoprazole in pregnant women. Studies in animals have shown reproductive toxicity. Preclinical studies revealed no evidence of impaired fertility or teratogenic effects (see section 5.3). The potential risk for humans is unknown. Pantoprazole should not be used during pregnancy.

Breast-feeding

Pantoprazole/metabolites have been identified in human milk. The effect of pantoprazole on newborns/infants is unknown. SOMAC Control should not be used during breast-feeding.

Fertility

There was no evidence of impaired fertility following the administration of pantoprazole in animal studies (see section 5.3).

4.7 Effects on ability to drive and use machines

SOMAC Control has no or negligible influence on the ability to drive and use machines. However adverse reactions such as dizziness and visual disturbances may occur (see section 4.8). If affected, patients should not drive or use machines.

4.8 Undesirable effects

Summary of the safety profile

Approximately 5% of patients can be expected to experience adverse reactions.

Tabulated list of adverse reactions

The following adverse reactions have been reported with pantoprazole. Within the following table, adverse reactions are ranked under the MedDRA frequency classification: 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 ($< 1/10,000$), not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 1. Adverse reactions with pantoprazole in clinical trials and post-marketing experience

Frequency System organ class	Common	Uncommon	Rare	Very rare	Not known
Blood and lymphatic system disorders			Agranulocytosis	Thrombocytopenia; Leukopenia; Pancytopenia	
Immune system disorders			Hypersensitivity (incl. anaphylactic reactions and anaphylactic shock)		
Metabolism and nutrition disorders			Hyperlipidaemias and lipid increases (triglycerides, cholesterol); Weight changes		Hyponatraemia; Hypomagnesaemia; Hypocalcaemia ⁽¹⁾ Hypokalaemia ⁽¹⁾
Psychiatric disorders		Sleep disorders	Depression (and all aggravations)	Disorientation (and all aggravations)	Hallucination; Confusion (especially in pre-disposed patients, as well as the aggravation of these symptoms in case of pre-existence)
Nervous system disorders		Headache; Dizziness	Taste disorders		Paraesthesia

Frequency System organ class	Common	Uncommon	Rare	Very rare	Not known
Eye disorders			Disturbances in vision / blurred vision		
Gastrointestinal disorders	Fundic gland polyps (benign)	Diarrhoea; Nausea / vomiting; Abdominal distension and bloating; Constipation; Dry mouth; Abdominal pain and discomfort			Microscopic colitis
Hepatobiliary disorders		Liver enzymes increased (transaminases, γ -GT)	Bilirubin increased		Hepatocellular injury; Jaundice; Hepatocellular failure
Skin and subcutaneous tissue disorders		Rash / exanthema / eruption; Pruritus	Urticaria; Angioedema		Stevens-Johnson syndrome; Lyell syndrome (TEN); Drug reaction with eosinophilia and systemic symptoms (DRESS); Erythema multiforme; Photosensitivity Subacute cutaneous lupus erythematosus (see section 4.4).
Musculoskeletal and connective tissue disorders		Fracture of wrist, hip and spine.	Arthralgia; Myalgia		
Renal and urinary disorders					Tubulointerstitial nephritis (TIN) (with possible progression to renal failure)
Reproductive system and breast disorders			Gynaecomastia		
General disorders and administration site conditions		Asthenia, fatigue and malaise	Body temperature increased; Oedema peripheral		

⁽¹⁾ Hypocalcaemia and/or hypokalaemia may be related to the occurrence of hypomagnesaemia (see section 4.4)

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

Doses up to 240 mg administered intravenously over 2 minutes were well tolerated. As pantoprazole is extensively protein bound, it is not readily dialysable.

In the case of overdose with clinical signs of intoxication, apart from symptomatic and supportive treatment, no specific therapeutic recommendations can be made.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Proton pump inhibitors, ATC code: A02BC02

Mechanism of action

Pantoprazole is a substituted benzimidazole which inhibits the secretion of hydrochloric acid in the stomach by specific blockade of the proton pumps of the parietal cells.

Pantoprazole is converted to its active form, a cyclic sulphenamide, in the acidic environment in the parietal cells where it inhibits the H⁺, K⁺-ATPase enzyme, i.e., the final stage in the production of hydrochloric acid in the stomach.

The inhibition is dose-dependent and affects both basal and stimulated acid secretion. In most patients, freedom from heartburn and acid reflux symptoms is achieved in 1 week. Pantoprazole reduces acidity in the stomach and thereby increases gastrin in proportion to the reduction in acidity. The increase in gastrin is reversible. Since pantoprazole binds to the enzyme distal to the receptor level, it can inhibit hydrochloric acid secretion independently of stimulation by other substances (acetylcholine, histamine, gastrin). The effect is the same whether the active substance is given orally or intravenously.

The fasting gastrin values increase under pantoprazole. On short-term use, in most cases they do not exceed the upper limit of normal. During long-term treatment, gastrin levels double in most cases. An excessive increase, however, occurs only in isolated cases. As a result, a mild to moderate increase in the number of specific endocrine (ECL) cells in the stomach is observed in a minority of cases during long-term treatment (simple to adenomatoid hyperplasia). However, according to the studies conducted so far, the formation of carcinoid precursors (atypical hyperplasia) or gastric carcinoids as were found in animal experiments (see section 5.3) have not been observed in humans.

During treatment with antisecretory medicinal products, serum gastrin increases in response to the decreased acid secretion. Also CgA increases due to decreased gastric acidity. The increased CgA level may interfere with investigations for neuroendocrine tumours.

Available published evidence suggests that proton pump inhibitors should be discontinued between 5 days and 2 weeks prior to CgA measurements. This is to allow CgA levels that might be spuriously elevated following PPI treatment to return to reference range.

Clinical efficacy and safety

In a retrospective analysis of 17 studies in 5960 patients with gastro-oesophageal reflux disease (GORD) who were treated with 20 mg pantoprazole monotherapy, the symptoms associated with acid reflux e.g., heartburn and acid regurgitation were evaluated according to a standardised methodology. Studies selected had to have at least one acid reflux symptom recording point at 2 weeks. GORD diagnosis in these studies was based on endoscopic assessment, with the exception of one study in which the inclusion of the patients was based on symptomatology alone.

In these studies, the percentage of patients experiencing complete relief from heartburn after 7 days was between 54.0% and 80.6% in the pantoprazole group. After 14 and 28 days, complete heartburn relief was experienced in 62.9% to 88.6% and 68.1% to 92.3% of the patients, respectively.

For the complete relief from acid regurgitation, similar results were obtained as for heartburn. After 7 days the percentage of patients experiencing complete relief from acid regurgitation was between 61.5% and 84.4%, after 14 days between 67.7% and 90.4%, and after 28 days between 75.2% and 94.5%, respectively.

Pantoprazole was consistently shown to be superior to placebo and H2RA and non-inferior to other PPIs. Acid-reflux symptom relief rates were largely independent of the initial GORD stage.

5.2 Pharmacokinetic properties

Pharmacokinetics do not vary after single or repeated administration. In the dose range of 10 to 80 mg, the plasma kinetics of pantoprazole are linear after both oral and intravenous administration.

Absorption

Pantoprazole is completely and rapidly absorbed after oral administration. The absolute bioavailability from the tablet was found to be about 77%. On average, at about 2.0 h - 2.5 h post administration (t_{max}) of a single 20 mg oral dose, the maximum serum concentrations (C_{max}) of about 1-1.5 $\mu\text{g/mL}$ are achieved, and these values remain constant after multiple administration. Concomitant intake of food had no influence on bioavailability (AUC or C_{max}), but increased the variability of the lag-time (t_{lag}).

Distribution

Volume of distribution is about 0.15 L/kg and serum protein binding is about 98%.

Biotransformation

Pantoprazole is almost exclusively metabolised in the liver.

Elimination

Clearance is about 0.1 L/h/kg, and terminal half-life ($t_{1/2}$) about 1 h. There were a few cases of subjects with delayed elimination. Due to the specific binding of pantoprazole to the proton pumps within the parietal cell, the elimination half-life does not correlate with the much longer duration of action (inhibition of acid secretion).

Renal elimination represents the major route of excretion (about 80%) for the metabolites of pantoprazole; the rest is excreted with the faeces. The main metabolite in both serum and urine is desmethylpantoprazole, which is conjugated with sulphate. The half-life of the main metabolite (about 1.5 h) is not much longer than that of pantoprazole.

Special populations

Renal impairment

No dose reduction is recommended when pantoprazole is administered to patients with impaired renal function (including patients on dialysis, which removes only negligible amounts of pantoprazole). As with healthy subjects, the half-life of pantoprazole is short. Although the main metabolite has a longer half-life (2-3 h), excretion is still rapid and thus accumulation does not occur.

Hepatic impairment

After administration of pantoprazole to patients with liver impairment (Child-Pugh classes A, B and C) the half-life values increased to between 3 and 7 h and the AUC values increased by a factor of 3-6, whereas the C_{max} only increased slightly by a factor of 1.3 compared with healthy subjects.

Elderly

The slight increase in AUC and C_{max} in elderly volunteers compared with younger subjects was not clinically relevant.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity.

In the 2-year carcinogenicity studies in rats, neuroendocrine neoplasms were found. In addition, squamous cell papillomas were found in the forestomach of rats in one study. The mechanism leading to the formation of gastric carcinoids by substituted benzimidazoles has been carefully investigated and allows the conclusion that it is a secondary reaction to the massively elevated serum gastrin levels occurring in the rat during chronic high-dose treatment.

In the 2-year rodent studies an increased number of liver tumours was observed in rats (in one rat study only) and in female mice and was interpreted as being due to pantoprazole's high metabolic rate in the liver.

A slight increase of neoplastic changes of the thyroid was observed in the group of rats receiving the highest dose (200 mg/kg) in one 2-year study. The occurrence of these neoplasms is associated with the pantoprazole-induced changes in the breakdown of thyroxine in the rat liver. As the therapeutic dose in man is low, no side effects on the thyroid glands are expected.

In a peri-postnatal rat reproduction study designed to assess bone development, signs of offspring toxicity (mortality, lower mean body weight, lower mean body weight gain and reduced bone growth) were observed at exposures (C_{max}) approximately 2x the human clinical exposure. By the end of the recovery phase, bone parameters were similar across groups and body weights were also trending toward reversibility after a drug-free recovery period. The increased mortality has only been reported in pre-weaning rat pups (up to 21 days age) which is estimated to correspond to infants up to the age of 2 years old. The relevance of this finding to the paediatric population is unclear. A previous peri-postnatal study in rats at slightly lower doses found no adverse effects at 3 mg/kg compared with a low dose of 5 mg/kg in this study. Investigations revealed no evidence of impaired fertility or teratogenic effects.

Penetration of the placenta was investigated in the rat and was found to increase with advanced gestation. As a result, concentration of pantoprazole in the foetus is increased shortly before birth.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core

Sodium carbonate, anhydrous
Mannitol (E421)
Crospovidone
Povidone K90
Calcium stearate

Coating

Hypromellose
Povidone K25
Titanium dioxide (E171)
Yellow iron oxide (E172)
Propylene glycol (E1520)
Methacrylic acid-ethyl acrylate copolymer (1:1)
Sodium laurilsulfate
Polysorbate 80
Triethyl citrate

Printing ink

Shellac
Red iron oxide (E172)
Black iron oxide (E172)
Yellow iron oxide (E172)
Ammonia solution, concentrated

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Alu/Alu blisters with or without cardboard reinforcement containing 7 or 14 gastro-resistant tablets

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

Takeda GmbH
Byk-Gulden-Str. 2
D-78467 Konstanz
Germany
medinfoEMEA@takeda.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/516/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12 June 2009

Date of latest renewal: 21 February 2014

10. DATE OF REVISION OF THE TEXT

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

ANNEX II

- A. MANUFACTURER(S) 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(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Takeda GmbH
Production site Oranienburg
Lehnitzstraße 70-98
D-16515 Oranienburg
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product not subject to medical prescription.

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.

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

- **Risk management plan (RMP)**

Not applicable.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON FOR BLISTER

OUTER CARTON FOR BLISTER WITH CARDBOARD REINFORCEMENT

1. NAME OF THE MEDICINAL PRODUCT

SOMAC Control 20 mg gastro-resistant tablets
pantoprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gastro-resistant tablet contains 20 mg pantoprazole (as sodium sesquihydrate).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

7 gastro-resistant tablets
14 gastro-resistant tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Tablets should be swallowed whole.
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

Takeda GmbH
Byk-Gulden-Str. 2
D-78467 Konstanz
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/516/001-004

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

For short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.
Take one tablet (20 mg) per day. Do not exceed this dose. This medicine may not bring immediate relief.
Relieves heartburn

16. INFORMATION IN BRAILLE

SOMAC Control 20 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

Not applicable

PARTICULARS TO APPEAR ON THE INTERMEDIATE PACKAGING

CARDBOARD REINFORCEMENT

1. NAME OF THE MEDICINAL PRODUCT

SOMAC Control 20 mg gastro-resistant tablets
pantoprazole

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gastro-resistant tablet contains 20 mg pantoprazole (as sodium sesquihydrate).

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

7 gastro-resistant tablets
14 gastro-resistant tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Tablets should be swallowed whole.
Read the package leaflet before 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

Takeda GmbH
Byk-Gulden-Str. 2
D-78467 Konstanz
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/09/516/001-004

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Batch

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15. INSTRUCTIONS ON USE

For short-term treatment of reflux symptoms (e.g. heartburn, acid regurgitation) in adults.
Take one tablet (20 mg) per day. Do not exceed this dose. This medicine may not bring immediate relief.
Relieves heartburn.

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

SOMAC Control 20 mg gastro-resistant tablets
pantoprazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Takeda GmbH

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

SOMAC Control 20 mg gastro-resistant tablets pantoprazole

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.
- You should not take SOMAC Control tablets for more than 4 weeks without consulting a doctor.

What is in this leaflet

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

1. What SOMAC Control is and what it is used for

SOMAC Control contains the active substance pantoprazole, which blocks the ‘pump’ that produces stomach acid. Hence it reduces the amount of acid in your stomach.

SOMAC Control is used for the short-term treatment of reflux symptoms (for example heartburn, acid regurgitation) in adults.

Reflux is the backflow of acid from the stomach into the gullet (“foodpipe”), which may become inflamed and painful. This may cause you symptoms such as a painful burning sensation in the chest rising up to the throat (heartburn) and a sour taste in the mouth (acid regurgitation).

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with SOMAC Control, but this medicine is not meant to bring immediate relief. It may be necessary to take the tablets for 2-3 consecutive days to relieve the symptoms.

You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

2. What you need to know before you take SOMAC Control

Do not take SOMAC Control

- if you are allergic to pantoprazole or to any of the other ingredients of this medicine (listed in section 6)
- if you are taking HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection). See ‘Other medicines and SOMAC Control’.

Warnings and precautions

Talk to your doctor or pharmacist before taking SOMAC Control

- if you have been treated for heartburn or indigestion continuously for 4 or more weeks
- if you are over 55 years old and taking non-prescription indigestion treatment on a daily basis
- if you are over 55 years old with any new or recently changed reflux symptoms
- if you have previously had a gastric ulcer or stomach surgery
- if you have liver problems or jaundice (yellowing of skin or eyes)
- if you regularly see your doctor for serious complaints or conditions
- if you are due to have an endoscopy or a breath test called a C-urea test.
- if you have ever had a skin reaction after treatment with a medicine similar to SOMAC Control that reduces stomach acid.
- if you are due to have a specific blood test (Chromogranin A)
- if you are taking HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection) at the same time as pantoprazole, ask your doctor for specific advice.

Do not take this product for longer than 4 weeks without consulting your doctor. If your reflux symptoms (heartburn or acid regurgitation) persist for longer than 2 weeks, consult your doctor who will decide about the need for long-term intake of this medicine.

If you take SOMAC Control for longer periods, this may cause additional risks, such as:

- reduced absorption of Vitamin B₁₂, and Vitamin B₁₂ deficiency if you already have low body stores of Vitamin B₁₂. Please contact your doctor if you notice any of the following symptoms, which could indicate low levels of Vitamin B₁₂:
 - Extreme tiredness or lack of energy
 - Pins and needles
 - Sore or red tongue, mouth ulcers
 - Muscle weakness
 - Disturbed vision
 - Problems with memory, confusion, depression
- fracture of your hip, wrist or spine, especially if you already have osteoporosis (reduced bone density) or if your doctor has told you that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- falling magnesium levels in your blood (potential symptoms: fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate). Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. You should talk to your doctor if you have been using this product for more than 4 weeks. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Tell your doctor immediately, before or after taking this medicine, if you notice any of the following symptoms, which could be a sign of another, more serious, disease:

- an unintentional loss of weight (not related to a diet or an exercise programme)
- vomiting, particularly if repeated
- vomiting blood; this may appear as dark coffee grounds in your vomit
- you notice blood in your stools; which may be black or tarry in appearance
- difficulty in swallowing or pain when swallowing
- you look pale and feel weak (anaemia)
- chest pain
- stomach pain
- severe and/or persistent diarrhoea, because this medicine has been associated with a small increase in infectious diarrhoea.
- if you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with SOMAC Control. Remember to also mention any other ill-effects like pain in your joints.
- Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) and erythema multiforme, have been reported in association with pantoprazole treatment. Stop using pantoprazole and seek

medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

Your doctor may decide that you need some tests.

If you are due to have a blood test, tell your doctor that you are taking this medicine.

You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with SOMAC Control, but this medicine is not meant to bring immediate relief. You should not take it as a preventive measure.

If you have been suffering from repetitive heartburn or indigestion symptoms for some time, remember to see your doctor regularly.

Children and adolescents

SOMAC Control should not be used by children and adolescents under 18 years of age due to a lack of safety information in this younger age group.

Other medicines and SOMAC Control

Tell your doctor or pharmacist if you are using, have recently used or might use any **other** medicines.

SOMAC Control may stop certain other medicines from working properly. Especially medicines containing one of the following active substances:

- HIV protease inhibitors such as atazanavir, nelfinavir (for the treatment of HIV-infection). You must not use SOMAC Control if you are taking HIV protease inhibitors. See 'Do not take SOMAC Control'.
- ketoconazole (used for fungal infections).
- warfarin and phenprocoumon (used to thin blood and prevent clots). You may need further blood tests.
- methotrexate (used to treat rheumatoid arthritis, psoriasis, and cancer) – if you are taking methotrexate your doctor may temporarily stop your SOMAC Control treatment because pantoprazole can increase levels of methotrexate in the blood.

Do not take SOMAC Control with other medicines which limit the amount of acid produced in your stomach, such as another proton pump inhibitor (omeprazole, lansoprazole or rabeprazole) or an H² antagonist (e.g. ranitidine, famotidine).

However, you may take SOMAC Control with antacids (e.g. magaldrate, alginic acid, sodium bicarbonate, aluminium hydroxide, magnesium carbonate, or combinations thereof), if needed.

Talk to your doctor before taking SOMAC Control if you are due to have a specific urine test (for THC; Tetrahydrocannabinol).

Pregnancy and, breast-feeding and fertility

You should not take this medicine if you are pregnant or while breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

If you experience side effects like dizziness or disturbed vision, you should not drive or use machines.

SOMAC Control contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take SOMAC Control

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet a day. Do not exceed this recommended dose of 20 mg pantoprazole daily.

You should take this medicine for at least 2-3 consecutive days. Stop taking SOMAC Control when you are completely symptom-free. You may experience relief from your acid reflux and heartburn symptoms after just one day of treatment with SOMAC Control, but this medicine is not meant to bring immediate relief.

If you have no symptom-relief after taking this medicine for 2 weeks continuously, consult your doctor.

Do not take SOMAC Control tablets for more than 4 weeks without consulting your doctor.

Take the tablet before a meal, at the same time every day. You should swallow the tablet whole with some water. Do not chew or break the tablet.

If you take more SOMAC Control than you should

Tell your doctor or pharmacist if you have taken more than the recommended dose. If possible take your medicine and this leaflet with you.

If you forget to take SOMAC Control

Do not take a double dose to make up for the forgotten dose. Take your next, normal dose, the next day, at your usual time.

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 immediately or contact the casualty department at your nearest hospital, if you get any of the following **serious side effects**. Stop taking this medicine straight away, but take this leaflet and/or the tablets with you.

- **Serious allergic reactions (frequency rare: may affect up to 1 in 1,000 people):** hypersensitivity reactions, so-called anaphylactic reactions, anaphylactic shock and angioedema. Typical symptoms are: swelling of the face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing, hives (nettle rash), severe dizziness with very fast heartbeat and heavy sweating.
- **Serious skin reactions (frequency not known: frequency cannot be estimated from the available data):**
you may notice one or more of the following

- rash with swelling, blistering or peeling of the skin, losing skin and bleeding around eyes, nose, mouth or genitals and rapid deterioration of your general health, or rash particularly in areas of skin exposed to the sun. You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes.
 - reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
 - widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- **Other serious reactions (frequency not known):**
yellowing of the skin and eyes (due to severe liver damage), or fever, rash, and enlarged kidneys sometimes with painful urination, and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

Other side effects include:

- **Common side effects:** (may affect up to 1 in 10 people)
benign polyps in the stomach
- **Uncommon side effects** (may affect up to 1 in 100 people)
headache; dizziness; diarrhoea; feeling sick, vomiting; bloating and flatulence (wind); constipation; dry mouth; bellyache and discomfort; skin rash or hives; itching; feeling weak, exhausted or generally unwell; sleep disorders; increase in liver enzymes in a blood test; fracture in the hip, wrist or spine.
- **Rare side effects:** (may affect up to 1 in 1,000 people)
distortion or complete lack of the sense of taste; disturbances in vision such as blurred vision; pain in the joints; muscle pains; weight changes; raised body temperature; swelling of the extremities; depression; increased bilirubin and fat levels in blood (seen in blood tests), breast enlargement in males; high fever and a sharp drop in circulating granular white blood cells (seen in blood tests).
- **Very rare side effects** (may affect up to 1 in 10,000 people)
disorientation; reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells, as well as platelets (seen in blood tests).
- **Not known:** (frequency cannot be estimated from the available data)
hallucination, confusion (especially in patients with a history of these symptoms); decreased level of sodium, magnesium, calcium or potassium in blood (see section 2); rash, possibly with pain in the joints; feeling of tingling, prickling, pins and needles, burning sensation or numbness, inflammation in the large bowel, that causes persistent watery diarrhoea.

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 SOMAC Control

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 carton and the blister after 'EXP'. The expiry date refers to the last day of that month.

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

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 SOMAC Control contains

- The active substance is pantoprazole. Each tablet contains 20 mg pantoprazole (as sodium sesquihydrate).
- The other ingredients are:
Core: sodium carbonate (anhydrous), mannitol(E421), crospovidone, povidone K90, calcium stearate.
Coating: hypromellose, povidone, titanium dioxide (E171), yellow iron oxide (E172), propylene glycol (E1520), methacrylic acid-ethyl acrylate copolymer, sodium laurilsulfate, polysorbate 80, triethyl citrate.
Printing ink: shellac, red, black and yellow iron oxide (E172) and ammonia solution, concentrated.

What SOMAC Control looks like and contents of the pack

The gastro-resistant tablets are yellow, oval, biconvex film-coated tablets imprinted with "P20" on one side.

SOMAC Control is available in Alu/Alu blisters with or without cardboard reinforcement. Packs containing 7 or 14 gastro-resistant tablets. Not all pack sizes may be marketed.

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

The following recommendations for lifestyle and dietary changes may also help to relieve heartburn or acid related symptoms.

- Avoid large meals
- Eat slowly
- Stop smoking
- Reduce alcohol and caffeine consumption
- Reduce weight (if overweight)
- Avoid tight-fitting clothing or belts
- Avoid eating less than three hours before bedtime
- Elevate bedhead (if you suffer from nocturnal symptoms)
- Reduce intake of food that can cause heartburn. These might include: Chocolate, peppermint, spearmint, fatty and fried food, acidic food, spicy food, citrus fruits and fruit juices, tomatoes.