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Ontilyv (*opicapone*)

Ħarsa ġenerali lejn Ontilyv u għalfejn huwa awtorizzat fl-UE

X'inhu Ontilyv u għal xiex jintuża?

Ontilyv huwa mediċina li tintuża biex tikkura adulti bil-marda ta' Parkinson, disturb progressiv fil-moħħ li jikkawża rogħda u ebusija tal-muskoli, u li jwassal biex il-moviment ikun aktar bil-mod.

Ontilyv jintuża bħala żieda f'pazjenti li jkollhom fluttwazzjonijiet fil-kapaċità li jiċċaqalqu waqt li jkunu qed jiġu kkurati b'mediċini ta' kombinazzjoni għall-marda ta' Parkinson li fihom levodopa u inibitur ta' DOPA decarboxylase (DDCI).

Il-fluttwazzjonijiet iseħħu meta l-effetti tal-medikazzjoni ta' kombinazzjoni ma jibqgħux jinħassu u s-sintomi jfeġġu mill-ġdid qabel id-doża li jmiss. Dawn huma marbuta ma' tnaqqis fl-effett ta' levodopa. Matul dawn il-fluttwazzjonijiet motorji l-pazjent jesperjenza bidliet għal għarrieda bejn li jkun 'on' u li jkun kapaċi jiċċaqlaq, u li jkun 'off' u li jkollu diffikultà biex jiċċaqlaq. Ontilyv jintuża meta dawn il-fluttwazzjonijiet ma jkunux jistgħu jiġu kkurati bil-kombinazzjonijiet standard li fihom levodopa biss.

Din il-mediċina hija l-istess bħal Ongentys, li diġà hija awtorizzata fl-UE. Il-kumpanija li tipproduċi Ongentys qablet li d-*data* xjentifika tagħha tista' tintuża għal Ontilyv ('kunsens infurmat').

Ontilyv fih is-sustanza attiva opicapone.

Kif jintuża Ontilyv?

Il-mediċina tista' tinkiseb biss b'riċetta ta' tabib. Ontilyv jiġi bħala kapsuli li għandhom jittieħdu mill-ħalq. Id-doża rrakkomandata hija 50 mg, li tittieħed darba kuljum fil-ħin tal-irqad, għall-inqas siegħa qabel jew wara mediċini ta' kombinazzjoni ta' levodopa.

Għal iktar informazzjoni dwar l-użu ta' Ontilyv, ara l-fuljett ta' tagħrif jew ikkuntattja lit-tabib jew lill-ispiżjar tiegħek.

Kif jaħdem Ontilyv?

F'pazjenti bil-marda ta' Parkinson, iċ-ċelloli fil-moħħ li jipproduċu n-newrotrażmettitur dopamine jibdew imutu u b'hekk jonqos l-ammont ta' dopamine fil-moħħ. Għalhekk il-pazjenti jitilfu l-ħila li jikkontrollaw il-movimenti tagħhom b'mod affidabbli. Is-sustanza attiva f'Ontilyv, l-opicapone, taħdem biex iġġib lura l-livelli ta' dopamine fil-partijiet tal-moħħ li jikkontrollaw il-moviment u l-koordinazzjoni. Hija ssaħħaħ l-effetti ta' levodopa, kopja tan-newrotrażmettitur dopamine li tista' tingħata mill-ħalq. L-

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opicapone timblokka enzima li hija involuta fit-tkissir ta' levodopa fil-ġisem imsejħa catechol-O-methyl transferase (COMT). Minħabba dan levodopa tibqa' attiva tul aktar żmien. Dan jgħin sabiex jittejbu s-sintomi tal-marda ta' Parkinson's, bħalma huma l-ebusija fil-muskoli u l-moviment aktar bil-mod.

X'inhuma l-benefiċċji ta' Ontilyv li ħarġu mill-istudji?

Il-benefiċċji ta' Ontilyv fil-marda ta' Parkinson ġew investigati f'żewġ studji prinċipali. Fl-ewwel studju, 600 pazjent bi flutwazzjonijiet ingħataw Ontilyv, entacapone (mediċina oħra għall-marda ta' Parkinson) jew plaċebo (kura finta), flimkien mal-kombinazzjoni attwali tagħhom ta' levodopa / DDCI. Dan l-istudju ħares lejn kemm il-kuri rnexxielhom inaqqsu l-ħin meta l-pazjenti jkollhom iktar diffikultà biex jiċċaqalqu, li jissejħu "perjodi off". Wara 14-15-il ġimgħa, il-perjodi off tqassru b'117-il minuta (kważi sagħtejn) f'pazjenti li kienu qegħdin jieħdu Ontilyv 50 mg, meta mqabbla ma' 96 minuta (madwar siegħa u nofs) f'pazjenti li kienu qed jieħdu l-mediċina komparatur entacapone u 56 minuta (inqas minn 1 siegħa) f'pazjenti li kienu qed jieħdu plaċebo.

Fit-tieni studju, li ħares ukoll lejn it-tnaqqis fil-perjodi off, Ontilyv tqabbel ma' plaċebo f'427 pazjent li kienu qed jieħdu kombinazzjoni ta' levodopa / DDCI. Wara 14-15-il ġimgħa, il-perjodi off tqassru b'119-il minuta (kważi sagħtejn) f'pazjenti li kienu qegħdin jieħdu Ontilyv 50 mg, meta mqabbla ma' 64 minuta f'pazjenti li kienu qed jieħdu plaċebo.

Iż-żewġ studji ġew estiżi għal sena addizzjonali u kkonfermaw il-benefiċċji ta' Ontilyv meta użat fit-tul.

Fiż-żewġ studji, il-pazjenti kellhom perjodi off medji ta' madwar 6 sa 7 sigħat fil-bidu tal-istudju.

X'inhuma r-riskji assoċjati ma' Ontilyv?

L-effetti sekondarji l-aktar komuni b'Ontilyv huma disturbi fis-sistema nervuża (moħħ u korda spinali). Fost dawn, dyskinesia (diffikultà fil-kontroll tal-moviment) tista' taffettwa madwar 2 persuni minn kull 10). Għal-lista sħiħa tal-effetti sekondarji kollha rrappurtati b'Ontilyv, ara l-fuljett ta' tagħrif.

Ontilyv ma għandux jintuża fuq:

- pazjenti b'tumuri tal-glandoli adrenali (glandoli żgħar li jinsabu fuq il-kliewi) bħal pheochromocytoma u paraganglioma;
- pazjenti bi storja ta' sindrome newrolettika malinna (disturb fis-sistema nervuża li normalment ikun ikkawżat minn mediċini antipsikotiċi) jew rhabdomyolysis (tkissir tal-fibri muskolari);
- pazjenti li jieħdu mediċini magħrufin bħala inibituri ta' monoamine oxidase mhux selettivi (MAO), apparti meta jintużaw biex jikkuraw il-marda ta' Parkinson.

Għal-lista sħiħa ta' restrizzjonijiet, ara l-fuljett ta' tagħrif.

Għaliex Ontilyv ġie awtorizzat fl-UE?

Il-Kumitat għall-Prodotti Mediċinali għall-Użu mill-Bniedem (CHMP) tal-Aġenzija ddeċieda li l-benefiċċji ta' Ontilyv huma akbar mir-riskji tiegħu u li jista' jiġi awtorizzat għall-użu fl-UE. Ontilyv intwera li huwa aktar effettiv minn plaċebo u għall-inqas effettiv daqs il-komparatur entacapone fit-tnaqqis tal-perjodi off f'pazjenti bil-marda ta' Parkinson li jieħdu mediċini ta' kombinazzjoni ta' levodopa. Fir-rigward tas-sigurtà tiegħu, Ontilyv tqies li huwa komparabbli għal mediċini oħrajn tal-istess klassi.

X’miżuri qegħdin jittieħdu biex jiġi żgurat l-użu sigur u effettiv ta’ Ontilyv?

Fis-sommarju tal-karatteristiċi tal-prodott u fil-fuljett ta’ tagħrif ġew inklużi r-rakkomandazzjonijiet u l-prekawzjonijiet li għandhom ikunu segwiti mill-professjonisti fil-qasam tal-kura tas-saħħa u mill-pazjenti għall-użu sigur u effettiv ta’ Ontilyv.

Bħal fil-każ tal-mediċini kollha, id-*data* dwar l-użu ta’ Ontilyv hija ssorveljata kontinwament. L-effetti sekondarji ssuspettati rrappurtati b’Ontilyv huma evalwati bir-reqqa u kull azzjoni meħtieġa hi meħuda biex tipproteġi lill-pazjenti.

Informazzjoni oħra dwar Ontilyv

Aktar informazzjoni dwar Ontilyv tinstab fis-sit web tal-Aġenzija: ema.europa.eu/medicines/human/EPAR/ontilyv

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Ontilyv (*opicapone*)

An overview of Ontilyv and why it is authorised in the EU

What is Ontilyv and what is it used for?

Ontilyv is a medicine used to treat adults with Parkinson's disease, a progressive brain disorder that causes shaking and muscle stiffness, and slows movement.

Ontilyv is used as an add-on in patients who are having fluctuations in the ability to move while being treated with combination medicines for Parkinson's disease that contain levodopa and a DOPA decarboxylase inhibitor (DDCI).

Fluctuations happen when the effects of the combination medication wear off and symptoms re-emerge before the next dose is due. They are linked to a reduction in the effect of levodopa. During these motor fluctuations the patient experiences sudden switches between being 'on' and able to move, and being 'off' and having difficulty moving about. Ontilyv is used when these fluctuations cannot be treated with the standard levodopa-containing combinations alone.

This medicine is the same as Ongentys, which is already authorised in the EU. The company that makes Ongentys has agreed that its scientific data can be used for Ontilyv ('informed consent').

Ontilyv contains the active substance opicapone.

How is Ontilyv used?

The medicine can only be obtained with a prescription. Ontilyv is available as capsules to be taken by mouth. The recommended dose is 50 mg, taken once a day at bedtime, at least one hour before or after levodopa combination medicines.

For more information about using Ontilyv, see the package leaflet or contact your doctor or pharmacist.

How does Ontilyv work?

In patients with Parkinson's disease, the cells in the brain that produce the neurotransmitter dopamine begin to die and the amount of dopamine in the brain decreases. The patients then lose their ability to control their movements reliably. The active substance in Ontilyv, opicapone, works to restore the levels of dopamine in the parts of the brain that control movement and coordination. It enhances the effects of levodopa, a copy of the neurotransmitter dopamine that can be taken by mouth. Opicapone blocks an enzyme that is involved in the breakdown of levodopa in the body called catechol-O-methyl transferase (COMT). As a result, levodopa remains active for longer. This helps to improve the symptoms of Parkinson's disease, such as stiffness and slowness of movement.

What benefits of Ontilyv have been shown in studies?

The benefits of Ontilyv in Parkinson's disease were investigated in two main studies. In the first study, 600 patients with fluctuations were given Ontilyv, entacapone (another medicine for Parkinson's

disease) or placebo (a dummy treatment), in addition to their current levodopa / DDCI combination. This study looked at how well the treatments reduced the time when patients have more difficulty moving about, called 'off periods'. After 14-15 weeks, off periods were shortened by 117 minutes (almost 2 hours) in patients taking Ontilyv 50 mg, compared with 96 minutes (about 1 and a half hour) in patients taking the comparator medicine entacapone and 56 minutes (less than 1 hour) in patients taking placebo.

In the second study, which also looked at the reduction in off periods, Ontilyv was compared with placebo in 427 patients who were taking a levodopa / DDCI combination. After 14-15 weeks, off periods were shortened by 119 minutes (almost 2 hours) in patients taking Ontilyv 50 mg, compared with 64 minutes in patients taking placebo.

Both studies were extended for one additional year and confirmed the benefits of Ontilyv when used long-term.

In both studies, patients had average off periods of about 6 to 7 hours at the start of the study.

What are the risks associated with Ontilyv?

The most common side effects with Ontilyv are disorders of the nervous system (brain and spinal cord). Among these, dyskinesia (difficulty controlling movement) may affect around 2 in 10 people. For the full list of all side effects reported with Ontilyv, see the package leaflet.

Ontilyv must not be used in:

- patients with tumours of the adrenal glands (small glands located on top of the kidneys) such as pheochromocytoma and paraganglioma;
- patients with a history of neuroleptic malignant syndrome (a nervous system disorder usually caused by antipsychotic medicines) or rhabdomyolysis (breakdown of muscle fibres);
- patients taking medicines known as non-selective monoamine oxidase (MAO) inhibitors, except when used to treat Parkinson's disease.

For the full list of restrictions, see the package leaflet.

Why is Ontilyv authorised in the EU?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Ontilyv's benefits are greater than its risks and it can be authorised for use in the EU. Ontilyv was shown to be more effective than placebo and at least as effective as the comparator entacapone in reducing off periods in patients with Parkinson's disease taking levodopa combination medicines. Regarding its safety, Ontilyv was considered to be comparable to other medicines of the same class.

What measures are being taken to ensure the safe and effective use of Ontilyv?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ontilyv have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ontilyv are continuously monitored. Suspected side effects reported with Ontilyv are carefully evaluated and any necessary action taken to protect patients.

Other information about Ontilyv

Further information on Ontilyv can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ontilyv