1.3.1 Package Leaflet

PACKAGE LEAFLET: INFORMATION FOR THE USER

Memantine Synthon 10 mg, tabletten
Memantine Synthon 20 mg, tabletten
Memantine Synthon 5 mg + 10 mg +15 mg + 20 mg, tabletten
memantine hydrochloride

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 Memantine Synthon is and what it is used for

How does Memantine Synthon work
Memantine Synthon contains the active substance memantine hydrochloride. It belongs to a group of medicines known as anti-dementia medicines.

Memory loss in Alzheimer's disease is due to a disturbance of message signals in the brain.

The brain contains so-called N-methyl-D-aspartate (NMDA)-receptors that are involved in transmitting nerve signals important in learning and memory.

Memantine Synthon belongs to a group of medicines called NMDA-receptor antagonists. Memantine Synthon acts on these NMDA-receptors improving the transmission of nerve signals and the memory.

What is Memantine Synthon used for
Memantine Synthon is used for the treatment of patients with moderate to severe Alzheimer's disease.

2. What you need to know before you take Memantine Synthon

Do not take Memantine Synthon
- if you are **allergic to memantine hydrochloride or any of the other ingredients** of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Memantine Synthon

Take special care with Memantine Synthon:
- if you have a history of epileptic seizures
- if you have recently experienced a myocardial infarction (heart attack), or if you are suffering from congestive heart failure or from an uncontrolled hypertension (high blood pressure).

In these situations the treatment should be carefully supervised, and the clinical benefit of Memantine Synthon reassessed by your doctor on a regular basis.

If you suffer from renal impairment (kidney problems), your doctor should closely monitor your kidney function and if necessary adapt the Memantine Synthon doses accordingly.

The use of medicinal products called amantadine (for the treatment of Parkinson´s disease), ketamine (a substance generally used as an anaesthetic), dextromethorphan (generally used to treat cough) and other NMDA-antagonists at the same time should be avoided.

You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet) or if you are suffering from states of renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction (poor kidney function)) or severe infections of the urinary tract (structure that carries urine), as your doctor may need to adjust the dose of your medicine.

Children and adolescents
Memantine Synthon is not recommended for children and adolescents under the age of 18 years.

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

Memantine Synthon may change the effects of the following medicines and their dose may need to be adjusted by your doctor:

- amantadine, ketamine, dextromethorphan
- dantrolene, baclofen
- cimetidine, ranitidine, procainamide, quinidine, quinine, nicotine
- hydrochlorothiazide (or any combination with hydrochlorothiazide)
- anticholinergics (substances generally used to treat movement disorders or intestinal cramps).

- anticonvulsants (substances used to prevent and relieve seizures)
- barbiturates (substances generally used to induce sleep)
- dopaminergic agonists (substances such as L-dopa, bromocriptine)
- neuroleptics (substances used in the treatment of mental disorders)
- oral anticoagulants

If you go into hospital, let your doctor know that you are taking Memantine Synthon.

Memantine Synthon with food and drink
You should inform your doctor if you have recently changed or intend to change your diet substantially (e.g. from normal diet to strict vegetarian diet) or if you are suffering from states of renal tubulary acidosis (RTA, an excess of acid-forming substances in the blood due to renal dysfunction (poor kidney function))or severe infections of the urinary tract (structure that carries urine), as your doctor may need to adjust the dose of your medicine.

Pregnancy and breast-feeding
The use of Memantine Synthon **in pregnant women is not recommended**.

Breast-feeding
Women taking Memantine Synthon should **not breast-feed**.

Driving and using machines
Your doctor will tell you whether your illness allows you to drive and to use machines safely. Also, Memantine Synthon may change your reactivity, making driving or operating machinery inappropriate.

Memantine Synthon contains lactose
If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before taking this medicinal product.

3. How to take Memantine Synthon

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

Dose
<10 mg>
The recommended dose of Memantine Synthon for adults and elderly is 20 mg once a day.
In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme:

week 1	half a 10 mg tablet
week 2	one 10 mg tablet
week 3	one and a half 10 mg tablet
week 4 and beyond	two 10 mg tablets once a day

The recommended dose can also be achieved by using a treatment initiation

pack.
The usual starting dose is half a tablet once a day (1x 5 mg) for the first week. This is increased to one tablet once a day (1x 10 mg) in the second week and to 1 and a half tablet once a day in the third week. From the fourth week on, the usual dose is 2 tablets once a day (1x 20 mg).

<20 mg>
The recommended dose of Memantine Synthon for adults and elderly patients is 20 mg once a day.
In order to reduce the risk of side effects this dose is achieved gradually by the following daily treatment scheme. For up-titration other tablet strengths are available.
At the beginning of treatment you will start by using Memantine Synthon 5 mg film-coated tablets once a day. This dose will be increased weekly by 5 mg until the recommended (maintenance) dose is reached. The recommended maintenance dose is 20 mg once a day, which is reached at the beginning of the 4th week.
<treatment initiation pack>
The recommended treatment dose of 20 mg per day is achieved by a gradual increase of the Memantine Synthon dose during the first 3 weeks of treatment. The treatment scheme is also indicated on the treatment initiation pack. Take one tablet once a day.

Week 1 (day 1-7):
Take one 5 mg tablet once a day (yellow, oval, biconvex) for 7 days.

Week 2 (day 8-14):
Take one 10 mg tablet once a day (white, round, biconvex) for 7 days.

Week 3 (day 15-21):
Take one 15 mg tablet once a day (orange-brown, round, biconvex) for 7 days.

Week 4 (day 22-28):
Take one 20 mg tablet per day (pink, oval, biconvex) for 7 days.

week 1	5 mg tablet
week 2	10 mg tablet
week 3	15 mg tablet
week 4 and beyond	20 mg tablets once a day

Maintenance dose
The recommended daily dose is 20 mg once a day.
For continuation of the treatment, other tablet strengths are available. Please consult your doctor.

Renal impairment If you have impaired kidney function, your doctor will decide upon a dose that suits your condition. In this case, monitoring of your kidney function should be performed by your doctor at specified intervals.

<10 mg>

Breaking the tablet
Place the tablet with the round side on a hard surface, the score line should face upwards. Press with the forefinger and thumb of the same hand on either side of the score line and push down until the tablet breaks as shown in the illustration.

<20 mg>
Breaking the tablet
Place the tablet with the round side on a hard surface, the score line should face upwards. Press with the forefinger and thumb of the same hand on either side of the score line and push down until the tablet breaks as shown in the illustration.

Administration
Memantine Synthon should be administered orally once a day. To benefit from your medicine you should take it regularly every day at the same time of the day. The tablets should be swallowed with some water. The tablets can be taken with or without food.

Duration of treatment
Continue to take Memantine Synthon as long as it is of benefit to you. Your doctor should assess your treatment on a regular basis.

If you take more Memantine Synthon than you should
In general, taking too much Memantine Synthon should not result in any harm to you. You may experience increased symptoms as described in section 4, Possible side effects.

If you take a large overdose of Memantine Synthon, contact your doctor or get medical advice, as you may need medical attention.

If you forget to take Memantine Synthon
If you find you have forgotten to take your dose of Memantine Synthon, wait and take your next dose at the usual time.
Do not take a double dose to make up for a forgotten dose.

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.

In general, the observed side effects are mild to moderate.

Common (may affect up to 1 in 10 people)
Headache • sleepiness • constipation • elevated liver function tests • dizziness • balance disorders • high blood pressure • shortness of breath • drug hypersensitivity

Uncommon (may affect up to 1 in 100 people)
Tiredness • fungal infections • confusion • hallucinations • vomiting • abnormal gait • heart failure • venous blood clotting (thrombosis/thromboembolism)

Very rare (may affect up to 1 in 10,000 people)
Seizures

Not known (frequency cannot be estimated from the available data)
Inflammation of the pancreas • inflammation of the liver (hepatitis) • Psychotic reactions

Alzheimer's disease has been associated with depression, suicidal ideation and suicide. These events have been reported in patients treated with Memantine Synthon.

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 Nederlands Bijwerkingen Centrum Lareb Website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Memantine Synthon

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

This medicinal product does not require any special storage conditions.

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 Memantine Synthon contains

- The active substance is memantine hydrochloride. Each film-coated tablet contains 10 20 5/10/15/20 mg of memantine hydrochloride equivalent to 8.31 16.62 4.15/8.31/12.46/16.62 mg memantine.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, talc and magnesium stearate, all in the tablet core; and lactose monohydrate, hypromellose, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172) and macrogol 4000 and additional for Memantine 5 mg, 15 mg and 20 mg tablets iron oxide yellow (E172) and for the Memantine Synthon 15 mg and 20 mg tablets iron oxide red (E172), all in the tablet coating.

What Memantine Synthon looks like and contents of the pack

<10 mg>
Memantine Synthon10 mg film-coated tablets are presented as white, round, biconvex tablets (8 mm) with a score line on one side and debossed with 'M9MN' and '10' on the other side. The tablet can be divided into equal halves.

Memantine Synthon film-coated tablets are available in blister packs of:
blisters containing 10, 14, 20, 28, 30, 42, 50, 56, 60, 98, 100, 112 or 120 tablets and a Unit dose blister containing 30x1 tablet
and/or blisters containing 90 tablets

Not all pack sizes may be marketed.

<20 mg>
Memantine Synthon 20 mg film-coated tablets are presented as pink, oval, biconvex tablets (13.5 x 6.6 mm) with a score line on one side and debossed with 'M9MN 20' on the other side. The tablet can be divided into equal halves.

Memantine Synthon film-coated tablets are available in blister packs of:
blisters containing 10, 14, 20, 28, 30, 42, 50, 56, 60, 90, 98, 100, 112 or 120 tablets and a Unit dose blister containing 30x1 tablet

Not all pack sizes may be marketed.

<treatment initiation pack>
Memantine Synthon 5 mg film-coated tablets are presented as yellow oval biconvex tablets (8 x 4.5 mm), debossed with 'M9MN 5' on one side.
Memantine Synthon 10 mg film-coated tablets are presented as white, round, biconvex tablets (8 mm) with a.score line on one side and debossed with 'M9MN' and '10' on the other side. The tablet can be divided into equal halves.
Memantine Synthon 15 mg film-coated tablets are presented orange-brown round biconvex tablets (9.3 mm) with a score line on one side and debossed with 'M9MN 15' on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Memantine Synthon 20 mg film-coated tablets are presented as pink oval biconvex tablets (13.5 x 6.6 mm), with a score line on one side and debossed with 'M9MN 20' on the other side. The tablet can be divided into equal halves.

Each pack contains 28 tablets in 4 blisters with 7 tablets of 5 mg, 7 tablets of 10 mg, 7 tablets of 15 mg and 7 tablets of 20 mg.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Synthon BV
Microweg 22
6545 CM Nijmegen
Nederland

Manufacturer(s):
Synthon BV
Microweg 22
6545 CM Nijmegen
Nederland

Synthon Hispania S.L.
Castelló, 1
Polígono Las Salinas
08830 Sant Boi de Llobregat
Spanje

Genericon Pharma GmbH
Hafnerstrasse 211
A-8054 Graz
Oostenrijk

Vipharm S.A.
ul. A. i F. Radziwiłłów 9,
05-850 Ożarów Mazowiecki
Polen

INDUSTRIA QUIMICA Y FARMACEUTICA VIR, S.A.
Laguna 66-68-70. P.I. Urtinsa II,
Alcorcon 28923 Madrid
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

AT: Memantin Genericon 10 mg Filmtabletten
CZ: Memantine Vipharm 10 mg potahované tablet
EL: Memantine Synthon 10 mg
ES: Memantina VIR 10 mg comprimidos recubiertos con película EFG
NL: Memantine Synthon 10 mg, tabletten

UK: Memantine Synthon 10 mg film-coated tablets
SK: Memantine Vipharm 10 mg filmom obalené tablet
IS: ZALATINE 10 mg filmuhúðuð tafla
FI: Adaxor 10 mg tabletti, kalvopäällysteinen
HU: Memantine Vipharm 10 mg filmtabletta
PL: Memantine Vipharm

AT: Memantin Genericon 20 mg Filmtabletten
CZ: Memantine Vipharm 20 mg potahované tablet
FI: Adaxor 20 mg tabletti, kalvopäällysteinen
EL: Memantine Synthon 20 mg
ES: Memantina VIR 20 mg comprimidos recubiertos con película EFG
NL: Memantine Synthon 20 mg, tabletten
UK: Memantine Synthon 20 mg film-coated tablets
SK: Memantine Vipharm 20 mg filmom obalené tablet
IS: ZALATINE 20 mg filmuhúðuð tafla
HU: Memantine Vipharm 20 mg filmtabletta
PL: Memantine Vipharm

AT: Memantin Genericon 5 mg, 10 mg, 15 mg, 20 mg Filmtabletten (Starterpackung) /
EL: Memantine Synthon 5 mg + 10 mg + 15 mg + 20 mg
ES: Memantina VIR 5 mg + 10 mg + 15 mg + 20 mg comprimidos recubiertos con película EFG
NL: Memantine Synthon 5 mg + 10 mg +15 mg + 20 mg, tabletten
UK: Memantine Synthon Treatment Initiation Pack 5 mg + 10 mg + 15 mg + 20 mg film-coated tablets
FI: Adaxor aloituspakkaus 5 mg, 10 mg, 15 mg, 20 mg tabletti, kalvopäällysteinen /

This leaflet was last revised in September 2018.