Package leaflet: Information for the user

Movymia® 20 micrograms/80 microliters solution for injection

Teriparatide

▼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 using 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 Movymia® is and what it is used for

Movymia® contains the active substance teriparatide that is used to make the bones stronger, and to reduce the risk of fractures by stimulating bone formation.

Movymia® is used to treat osteoporosis in adults. Osteoporosis is a disease that causes your bones to become thin and fragile. This disease is especially common in women after the menopause, but it can also occur in men. Osteoporosis is also common in patients receiving medicines called corticosteroids.

2. What you need to know before you use Movymia®

Do not use Movymia®:
- if you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section 6).
- if you have high levels of calcium in your blood (hypercalcaemia).
- if you suffer from serious kidney problems.
- if you have ever had bone cancer or if other cancers have spread (metastasised) to your bones.
- if you have certain bone diseases. If you have a bone disease, tell your doctor.
- if you have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget's disease of bone (disease with abnormal bone changes). If you are not sure, ask your doctor.
- if you have had radiation therapy involving your bones.
- if you are pregnant or breast-feeding.

Warning and precautions
Movymia® may increase calcium in your blood or urine.
Talk to your doctor before or while using Movymia®:
- if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- if you suffer from kidney stones or have had kidney stones.
- if you suffer from kidney problems (moderate renal impairment).

Some patients get dizzy or get a fast heartbeat after the first few doses of Movymia®. For the first doses, inject Movymia® in a place where you can sit or lie down right away if you get dizzy.

The recommended treatment time of 24 months should not be exceeded.

Before inserting a cartridge in Movymia® Pen write down the batch (Lot) number of the cartridge and its first injection date on a calendar. The date of first injection should also be recorded on the outer carton of Movymia® (see the provided space on the box: {First use:}) (see section 3.).

Movymia® should not be used in growing adults.

Children and adolescents
Movymia® should not be used in children and adolescents (aged less than 18 years).

Other medicines and Movymia®
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
This is important, because some medicines (e.g. digoxin/digitalis, a medicine used to treat heart disease) may interact with teriparatide.

Pregnancy and breast-feeding
Do not use Movymia® if you are pregnant or breast-feeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of Movymia®. If you become pregnant while using Movymia®, Movymia® should be discontinued. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Some patients may feel dizzy after injecting Movymia®. If you feel dizzy you should not drive or use machines until you feel better.

Movymia® contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially "sodium-free".

3. How to use Movymia®

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

The recommended dose is 20 micrograms (corresponding to 80 microliters) given once a day by injection under the skin (subcutaneous injection) in the thigh or abdomen.
To help you remember to take your medicine, inject it at about the same time each day.
Movymia® can be injected at meal times. Inject Movymia® each day for as long as your doctor prescribes it for you. The total duration of treatment with Movymia® should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.
Your doctor may advise you to take Movymia® with calcium and vitamin D. Your doctor will tell you how much you should take each day.

Movymia® can be given with or without food.

Movymia® cartridges are designed to be used only with the Movymia® Pen reusable, multidose delivery system and compatible pen needles. The pen and injection needles are not included with Movymia®. However, for treatment initiation a cartridge and pen pack should be used containing one carton of Movymia® cartridge and one carton of Movymia® Pen.

Before the first use, insert the cartridge into the pen. For the correct use of this medicine it is very important to closely follow the detailed Instructions for Use of your pen which are provided with the pen.

Use a new injection needle for each injection to prevent contamination and safely dispose of the needle after use.
Never store your pen with the needle attached.
Never share your pen with others.
Do not use your Movymia® Pen to inject any other medicine (e.g. insulin).
The pen is customised for use with Movymia® only.
Do not refill the cartridge.
Do not transfer the medicine into a syringe.

You should inject Movymia® shortly after you take the pen with inserted cartridge out of the refrigerator. Put the pen with inserted cartridge back into the refrigerator immediately after you have used it. Do not remove the cartridge from the pen after each use. Store it in the cartridge sleeve during the whole 28-day treatment period.

Preparing the pen for use
- To ensure the correct administration of Movymia® always read the Instructions for Use of Movymia® Pen, which is included in the carton of the pen.
- Wash your hands before handling the cartridge or pen.
- Check the expiry date on the cartridge label before inserting the cartridge into the pen. Make sure that there are at least 28 days remaining before its expiry date. Insert the cartridge into the pen before the first use as detailed in the pen instructions. Write down the batch (Lot) number of each cartridge and its first injection date on a calendar. The date of first injection should also be recorded on the outer carton of Movymia® (see the provided space on the box: {First use:}).
- After inserting a new cartridge and before the first injection from this cartridge prime the pen according to the instructions which are provided. Do not prime again after the first dose.

Injecting Movymia®
- Before you inject Movymia®, clean your skin where you intend to inject (thigh or abdomen) as instructed by your doctor.
- Gently hold a fold of cleansed skin and insert the needle straight into the skin. Press the push button and hold it pressed in until the dose indication has returned to the start position.
- After your injection, leave the needle in the skin for six seconds to make sure that you receive the whole dose.
- As soon as you have finished the injection, attach the outer needle protective cap on the pen needle and screw the cap anti-clockwise to remove the pen needle. This will keep the remaining Movymia® sterile and prevent leaking from the pen. It will also stop air going back into the cartridge and the needle from clogging.
- Replace the cap on your pen. Leave the cartridge in the pen.

If you use more Movymia® than you should
If, by mistake, you have used more Movymia® than you should, contact your doctor or pharmacist.
The expected effects of overdose include nausea, vomiting, dizziness, and headache.

If you forget to use Movymia®
If you forget an injection or cannot use your medicine at your usual time, inject it as soon as possible on that day. Do not use a double dose to make up for a forgotten dose. Do not take more than one injection in the same day.

If you stop using Movymia®
If you are considering stopping Movymia® treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Movymia®.

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.

The most common side effects are pain in limb (which may affect more than 1 in 10 people). Other common side effects (affecting up to 1 in 10 people) include feeling sick, headache and dizziness. If you become dizzy (light-headed) after your injection, you should sit or lie down until you feel better. If you do not feel better, you should call a doctor before you continue treatment. Cases of fainting have occured after teriparatide use.

If you have discomfort around the area of the injection such as redness of the skin, pain, swelling, itching, bruising or minor bleeding (which can occur in up to 1 in 10 people), this should clear up in a few days or weeks. Otherwise tell your doctor.

Rarely, patients may suffer allergic reactions consisting of breathlessness, swelling of the face, rash and chest pain. These reactions usually occur soon after injection. In rare cases, serious and potentially life-threatening allergic reactions including anaphylaxis can occur.

Other side effects include:
Common (may affect up to 1 in 10 people):
- increase in blood cholesterol levels
- depression
- nerve pain in the leg
- feeling faint
- spinning sensation
- irregular heartbeats

- breathlessness
- increased sweating
- muscle cramps
- loss of energy
- tiredness
- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- vomiting
- a hernia of the tube that carries food to your stomach (hiatus hernia)
- low haemoglobin or red blood cell count (anaemia).

Uncommon (may affect up to 1 in 100 people):
- increased heart rate
- abnormal heart sound
- shortness of breath
- piles (haemorrhoids)
- leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some patients have had severe back cramps or pain which led to admission into hospital.
- increase in blood calcium level
- increase in blood uric acid level
- increase in an enzyme called alkaline phosphatase.

Rare (may affect up to 1 in 1,000 people):
- reduced kidney function, including renal failure
- swelling, mainly in the hands, feet and legs.

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

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Movymia®

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

Store in a refrigerator (2 °C – 8 °C). Do not freeze.
Keep the cartridge in the outer carton in order to protect from light.

You can use Movymia® for up to 28 days after the first injection, as long as the cartridge/pen with the cartridge inserted is stored in a refrigerator (2 °C to 8 °C).

Avoid placing the cartridge close to the ice compartment of the refrigerator to prevent freezing. Do not use Movymia® if it is, or has been, frozen.

Each cartridge should be properly disposed of after 28 days of first use, even if it is not completely empty.

Movymia® contains a clear and colourless solution. Do not use Movymia® if solid particles appear or if the solution is cloudy or coloured.

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 Movymia® contains
– The active substance is teriparatide. Each dose of 80 microliters contains 20 micrograms of teriparatide. One cartridge of 2.4 mL contains 600 micrograms of teriparatide (corresponding to 250 micrograms per mL).
– The other ingredients are: glacial acetic acid, mannitol, metacresol, sodium acetate trihydrate, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

What Movymia® looks like and contents of the pack
Movymia® is a colourless and clear solution. It is supplied in a cartridge. Each cartridge contains 2.4 mL of solution, enough for 28 doses.

Movymia® 20 micrograms/80 microliters solution for injection: 1 or 3 cartridge(s) packed in a plastic tray sealed with lid foil and packed in a carton.
Movymia® cartridge and pen pack: 1 Movymia® cartridge packed in a plastic tray sealed with lid foil and packed in a carton and 1 Movymia® Pen packed into a separate carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Germany

Manufacturer
Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest
Hungary

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

Thornton & Ross Ltd.
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Other sources of information
Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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