

MEGAPTH-G SOLUTION FOR INJECTION

Teriparatide (20 micrograms / 80 microliters)

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WHAT MEGAPTH-G IS USED FOR

MEGAPTH-G 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 people receiving corticosteroids.

HOW MEGAPTH-G WORKS

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

BEFORE YOU USE MEGAPTH-G

- When you must not use it

Do not use MEGAPTH-G

- if you are allergic to teriparatide or any of the other ingredients of this medicine (see section **Product description**)
- if you suffer from high calcium levels (pre-existing hypercalcaemia).
- if you suffer from serious kidney problems.
- if you have ever been diagnosed with bone cancer or other cancers that have spread (metastasized) 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.

Pregnancy and lactation

Do not use MEGAPTH-G 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 MEGAPTH-G. If you become pregnant, MEGAPTH-G should be discontinued. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

MEGAPTH-G may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using MEGAPTH-G:

- 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 are suffer from kidney or urinary tract stones or have a history of kidney or urinary tract stones.
- if you suffer from kidney problems (moderate renal impairment)

- Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because occasionally they may interact (e.g. digoxin/digitalis, a medicine used to treat heart disease).

HOW TO USE MEGAPTH-G

- How much to take

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 given once daily by

injection under the skin (subcutaneous injection) in the thigh or abdomen.

Children and adolescents:

MEGAPTH-G should not be used in children or in young adults if their bones have not finished growing (open epiphyses).

MEGAPTH-G should not be used in children.

Your doctor may advise you to take MEGAPTH-G with calcium and vitamin D. Your doctor will tell you how much you should take each day.

- How to take

Use as directed by your doctor or pharmacist daily to help you remember to take your medicine, inject it at about the same time each day.

MEGAPTH-G can be given with or without food.

- How long to use it

Inject MEGAPTH-G each day for as long as your doctor prescribes it for you. The total duration of treatment with MEGAPTH-G should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

- If you forget to use it

If you forget or cannot take MEGAPTH-G at your usual time, take it as soon as possible on that day. Do not take a double dose to make up for a forgotten dose. Do not take more than one injection in the same day. Do not try to make up for a missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The effects of overdose that might be expected include nausea, vomiting, dizziness, and headache

- If you stop taking MEGAPTH-G

If you and your doctor decide that you'll stop taking MEGAPTH-G, you can stop it abruptly.

MEGAPTH-G doesn't cause withdrawal symptoms, and your body doesn't become dependent on the drug. Withdrawal symptoms are side effects that can happen when you stop taking a drug that your body has become dependent on. Drug dependence occurs when your body needs a drug in order to feel normal.

However, your osteoporosis may get worse if you stop using MEGAPTH-G and don't start a different osteoporosis treatment. If your doctor suggests stopping MEGAPTH-G, they'll likely discuss a new treatment plan with you.

WHILE YOU ARE USING MEGAPTH-G

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking MEGAPTH-G.

Tell your doctor immediately if you become pregnant while taking this medication.

If you are about to have any blood tests, tell your doctor that you are using MEGAPTH-G. This medicine can cause small, temporary increases in blood calcium levels. If blood samples are taken, this needs to be done at least 16 hours after the last MEGAPTH-G injection.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. If you are considering stopping MEGAPTH-G treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with MEGAPTH-G.

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

- Things to be careful of

Some people get dizzy or get a fast heartbeat after the first few doses. For the first doses, inject MEGAPTH-G where you can sit or lie down right away if you get dizzy.

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

Driving and using machines

Some people may feel dizzy after injecting MEGAPTH-G. If you feel dizzy you should not drive or use machines until you feel better.

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 (frequency is very common, may affect more than 1 in 10 people) and feeling sick, headache and dizziness (frequency is common). 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 been reported in association with teriparatide use.

If you experience discomfort such as redness of the skin, pain, swelling, itching, bruising or minor bleeding around the area of the injection (frequency is common), this should clear up in a few days or weeks. Otherwise tell your doctor as soon as possible.

Some people may have experienced allergic reactions soon after injection, consisting of breathlessness, swelling of the face, rash and chest pain (frequency is rare). 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
- neuralgic pain in the leg
- feeling faint
- irregular heart beats
- breathlessness
- increased sweating
- muscle cramps
- loss of energy
- tiredness
- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- being sick (vomiting)
- a hernia of the tube that carries food to your stomach
- 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
- haemorrhoids (piles)
- accidental loss or leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some people have experienced severe back cramps or pain which lead to hospitalization.
- 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

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

- You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

STORAGE AND DISPOSAL OF MEGAPATH-G

- Storage

Keep out of the reach and sight of children.

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

Store in a refrigerator (2°C - 8°C).

After insertion of the cartridge into the pen, the combined pen and cartridge should be returned to the refrigerator immediately after use.

Do not freeze. Keep the cartridge in the outer carton in order to protect from light.

Do not store the injection device with the needle attached. Do not remove the cartridge from the pen after first use.

Keep out of reach of children

Shelf Life: 2 years

Chemical in-use stability has been demonstrated for 28 days at 2°C - 8°C.

From a microbiological point of view, once opened, the product may be stored for a maximum of 28 days within its shelf life at 2 °C to 8 °C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRODUCT DESCRIPTION

- What it looks like

MEGAPATH - G is available as 3 mL cartridge (siliconised Type I glass), with a plunger stopper and disc seal (aluminium and rubber liner seals),

packed in a plastic tray sealed with lid foil and packed in a carton.

Each cartridge contains 2.4 mL of solution corresponding to 28 doses of 20 micrograms (per 80 microliters).

- Ingredients

- Active Ingredient

Each ml of Teriparatide (r-Human Parathyroid Hormone) (1-34) Injection contains:

Teriparatide IHS 250 mcg

- Inactive Ingredients

Glacial acetic acid, Mannitol, Metacresol (preservative), Sodium acetate trihydrate, Hydrochloric acid (for pH adjustment), Sodium hydroxide (for pH adjustment), Water for injections

- MAL number

MAL xxxxxxxxxxxx

MANUFACTURER

Chemical Works of Gedeon Richter Plc. (Gedeon Richter Plc.)
Richter Gedeon utca 20., Debrecen, 4031, HUNGARY.

PRODUCT REGISTRATION HOLDER

MEGA LIFESCIENCES SDN. BHD.
B-28-02, The Ascent, Paradigm.
No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia.

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