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Package leaflet: Information for the patient

Somatrogon 24 mg/1.2 mL Solution for Injection in Pre-filled Pen

Somatrogon 60 mg/1.2 mL Solution for Injection in Pre-filled Pen

GENRYZON[®]

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

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you or the child in your care only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or those of the child in your care.
- If you or the child in your care get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What GENRYZON (Somatrogon) is and what it is used for
2. What you need to know before you use GENRYZON (Somatrogon)
3. How to use GENRYZON (Somatrogon)
4. Possible side effects
5. How to store GENRYZON (Somatrogon)
6. Contents of the pack and other information

1. What GENRYZON (Somatrogon) is and what it is used for

GENRYZON (Somatrogon) contains the active substance somatrogon, a modified form of human growth hormone. Natural human growth hormone is needed for bones and muscles to grow. It also helps your fat and muscle tissues to develop in the right amounts. GENRYZON (Somatrogon) is used to treat children and adolescents from 3 years of age who do not have enough growth hormone and are not growing at the normal rate.

The active substance in GENRYZON (Somatrogon) is made by ‘recombinant DNA technology’. This means that it is grown in cells that have been modified in the laboratory so that they can produce it.

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2. What you need to know before you use GENRYZON (Somatrogen)

Do not use GENRYZON (Somatrogen)

- If you or the child in your care are allergic to somatrogen (see Warnings and precautions) or any of the other ingredients of this medicine (listed in section 6).
- If you or the child in your care have an active tumour (cancer). Tell your doctor if you or the child in your care have or have had an active tumour. Tumours must be inactive, and you or the child in your care must have finished your anti-tumour treatment before starting treatment with GENRYZON (Somatrogen).
- If you or the child in your care have stopped growing because of closure of the growth plates (closed epiphyses) meaning that you or the child in your care have been told by your doctor that your bones have stopped growing.
- If you or the child in your care are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, multiple accidental trauma or similar conditions). If you or the child in your care are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you use growth hormone.

Warnings and precautions

Talk to your doctor before using GENRYZON (Somatrogen):

- If you or the child in your care develop a serious allergic reaction, stop using GENRYZON (Somatrogen), talk to your doctor right away. Sometimes serious allergic reactions such as hypersensitivity, including anaphylaxis or angioedema (difficulties breathing or swallowing, or swelling of the face, lips, throat or tongue) have occurred. If you or the child in your care have any of the following symptoms of a serious allergic reaction:
 - breathing problems
 - swelling of your face, mouth, and tongue
 - hives (nettle rash, lumps rising under the skin)
 - rash
 - fever
- If you or the child in your care have replacement therapy with corticosteroid medicines (glucocorticoids) you or the child in your care should consult your doctor regularly as you or the child in your care may need adjustment of your glucocorticoid dose.
- Your doctor should check at intervals how well the thyroid gland is working in you or the child in your care and if necessary may prescribe treatment or adjust the dose of existing treatment as this may be needed for GENRYZON (Somatrogen) to work properly.
- If you or the child in your care have Prader-Willi syndrome, you or the child should not be treated with GENRYZON (Somatrogen) unless you or the child in your care has growth hormone deficiency.
- Your doctor should monitor you or the child in your care for high blood sugar levels (hyperglycaemia) during treatment with GENRYZON (Somatrogen). If you or the child in your care are treated with insulin or other diabetes medicines, your doctor may need to adjust the insulin dose. If you or the child in your care have diabetes and associated severe/worsening eye disease you or the child in your care should not be treated with GENRYZON (Somatrogen).
- If you or the child in your care have ever had any kind of tumour (cancer).
- If you or the child in your care experience changes in vision, severe or frequent headaches, associated with feeling sick (nausea), vomiting, or experience lack of muscle

control or coordination of voluntary movements, such as walking or picking up objects, difficulty with speech, eye movement or swallowing, especially at the start of treatment, tell your doctor immediately. These could be signs of a temporary increase in pressure within the brain (intracranial hypertension).

- If you or the child in your care are seriously ill (for example, complications following open heart surgery, abdominal surgery, acute respiratory failure, multiple accidental trauma or similar conditions). If you or the child in your care are about to have, or have had, a major operation, or go into hospital for any reason, tell your doctor and remind the other doctors you are seeing that you or the child in your care use growth hormone.
- If you or the child in your care develop a severe stomach ache during treatment with GENRYZON (Somatrogen) as this could be a symptom of inflammation of the pancreas.
- If you or the child in your care notice a sideways curvature in your spine (scoliosis), you or the child in your care will need to be checked often by your doctor.
- If during growing you or the child in your care develop a limp or hip or knee pain, you or the child in your care should consult your doctor right away. These could be symptoms of bone disorders in your hip as this may happen during periods of rapid growth.
- If you or the child in your care are taking or stop taking oral contraception or hormonal replacement therapy with oestrogen, your doctor may recommend the dose of GENRYZON (Somatrogen) to be adjusted.

Other medicines and GENRYZON (Somatrogen)

Tell your doctor if you or the child in your care are using, have recently used or might use any other medicines.

- If you or the child in your care take replacement therapy with corticosteroid medicines (glucocorticoids), as these may reduce the effect of GENRYZON (Somatrogen) on growth. You or the child in your care should consult your doctor regularly, as you or the child in your care may need adjustment of your glucocorticoid dose.
- If you or the child in your care are treated with insulin or other diabetes medicines, you should consult with your doctor as you or your doctor may need to adjust the dose.
- If you or the child in your care are receiving treatment with thyroid hormones, your doctor may need to adjust the dose.
- If you or the child in your care are receiving oestrogen taken orally, you should consult your doctor as you or the child may need to adjust your dose of GENRYZON (Somatrogen).
- If you or the child in your care are receiving ciclosporin (a medicine that weakens the immune system after transplantation), you should consult your doctor as your doctor may need to adjust the dose.
- If you or the child in your care are receiving medicines to control epilepsy (anticonvulsants), you should consult your doctor as your doctor may need to adjust the dose.

Pregnancy and breast-feeding

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

GENRYZON (Somatrogen) has not been tested in pregnant women and it is not known if this medicine can harm your unborn baby. It is therefore preferable to avoid GENRYZON (Somatrogen) during pregnancy. If you are able to get pregnant, you should not use GENRYZON (Somatrogen) unless you are also using reliable contraception.

It is not known whether somatrogen can pass into breast milk. Tell your doctor or the doctor of the child in your care, if you or the child in your care are breast-feeding or plan to do so. Your doctor will then help you or the child in your care decide whether to stop breast-feeding, or whether to stop taking GENRYZON (Somatrogen), considering the benefit of breast-feeding to the baby and the benefit of GENRYZON (Somatrogen) to you or the child in your care.

Driving and using machines

GENRYZON (Somatrogen) does not affect the ability to drive and use machines.

GENRYZON (Somatrogen) contains sodium

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

GENRYZON (Somatrogen) contains metacresol

GENRYZON (Somatrogen) contains a preservative called metacresol. In very rare cases the presence of metacresol can cause inflammation (swelling) in muscles. If you or the child in your care experience muscle pain or pain at the injection site, inform your doctor.

3. How to use GENRYZON (Somatrogen)

This medicine will only be prescribed by a doctor who has experience with growth hormone treatment and who has confirmed your diagnosis or that of the child in your care.

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

The dose of GENRYZON (Somatrogen) to be injected will be decided by your doctor.

How much to use

Your doctor will work out your dose of GENRYZON (Somatrogen) from your body weight in kilograms. The recommended dose is 0.66 mg per kg body weight and is given once weekly. If you or the child in your care have been previously treated with daily growth hormone injections, your doctor will tell you to wait before taking the first dose of GENRYZON (Somatrogen) until the day after your last daily injection and then continue with GENRYZON (Somatrogen) once each week.

Do not change your dose unless your doctor has told you to.

How GENRYZON (Somatrogen) is given

- GENRYZON (Somatrogen) is available as a pre-filled pen in 2 different sizes (GENRYZON (Somatrogen) 24 mg and GENRYZON (Somatrogen) 60 mg). Based on the recommended dose your doctor or the doctor of the child in your care will prescribe the most appropriate pen size (see section 6 "Contents of the pack and other information").
- Before you or the child in your care use the pen for the first time, your/their doctor will show you how to use it. GENRYZON (Somatrogen) is given as an injection under the skin (subcutaneous injection) using a pre-filled pen. Do not inject it into a vein or muscle.

- The best place to give GENRYZON (Somatrogen) is in the abdomen (belly), thighs, buttocks or upper arms. Injections to the upper arms and buttocks should be given by the caregiver.
- Change the site of injection on your body, or on the body of the child in your care, each time a dose is administered.
- If more than one injection is required to deliver a complete dose, each should be administered at a different injection site.

Detailed instructions for use of the pre-filled pen are provided in the Medical Practitioner package insert.

When to use GENRYZON (Somatrogen)

You or the child in your care should use this medicine once a week on the same day each week.

You or the child in your care should record which day of the week you use GENRYZON (Somatrogen) to help you or the child in your care remember to inject this medicine once a week.

If necessary you or the child in your care can change the day of your/their weekly injection as long as it has been at least 3 days since you or the child in your care had your/their last injection. After selecting a new dosing day, continue giving yourself or the child in your care the injection on that day each week.

If you use more GENRYZON (Somatrogen) than you should

If you or the child in your care have injected more GENRYZON (Somatrogen) than you should have been given, contact your doctor straight away as your/their blood sugar levels may need to be checked.

If you forget to use GENRYZON (Somatrogen)

If you or the child in your care forgot to inject a dose and:

- It is 3 days or less since you or the child in your care should have used GENRYZON (Somatrogen), use it as soon as you remember. Then inject your/their next dose on your/their usual injection day.
- It is more than 3 days since you or the child in your care should have used GENRYZON (Somatrogen), skip the missed dose. Then inject your/their next dose as usual on your/their next scheduled day. A regular dosing day should be maintained.

Do not use a double dose to make up for a forgotten dose.

If you stop using GENRYZON (Somatrogen)

Do not stop using this medicine without talking to your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common: may affect more than 1 in 10 people

- Headache
- Bleeding, inflammation, itching, pain, redness, soreness, stinging, tenderness, or warmth at the injection site (injection site reactions)
- Fever (pyrexia)

Common: may affect up to 1 in 10 people

- Decrease in the number of red blood cells in the blood (anaemia)
- Increase in the number of eosinophils in the blood (eosinophilia)
- Decrease in the blood level of thyroid hormone (hypothyroidism)
- Allergic inflammation of the conjunctiva, the clear layer over the outside of the eye (allergic conjunctivitis)
- Joint pain (arthralgia)
- Pain in arms or legs

Uncommon: may affect up to 1 in 100 people

- The adrenal glands do not make enough steroid hormones (adrenal insufficiency)
- Rash

Other possible side effects not seen with GENRYZON (Somatrogen) but which have been reported in other growth hormone medicines treatment may include the following:

- Tissue growth (non cancerous or cancer)
- Type 2 diabetes
- Increased intracranial pressure (which causes symptoms such as strong headache, visual disturbances or vomiting)
- Numbness or tingling
- Joint or muscle pain
- Breast enlargement in boys and men
- Skin rash, reddening and itching
- Water retention (which shows as puffy fingers or swollen ankles)
- Facial swelling
- Pancreatitis (which causes symptoms of stomach pain, nausea, vomiting or diarrhoea)

In very rare cases the presence of metacresol can cause inflammation (swelling) in muscles. If you or the child in your care experience muscle pain or pain at the injection site, inform your doctor.

Reporting of side effects

If you or the child in your care get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store GENRYZON (Somatrogen)

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

The pre-filled pen should not be used more than 28 days after first use.

Before first use of GENRYZON (Somatrogen)

- Store in a refrigerator (2 °C - 8 °C).
- Keep GENRYZON (Somatrogen) in the outer carton in order to protect from light.
- Remove GENRYZON (Somatrogen) from the refrigerator prior to use. GENRYZON (Somatrogen) may be held at room temperature (up to 32 °C) for up to 4 hours.
- Do not use this medicine if you notice that the solution is cloudy or dark yellow. Do not use the medicine if it has flakes or particles.
- Do not shake the pen. Shaking can damage the medicine.

After first use of GENRYZON (Somatrogen)

- Use within 28 days after first use. Store in a refrigerator (2 °C - 8 °C). Do not freeze.
- Keep GENRYZON (Somatrogen) with the pen cap on in order to protect from light.
- Do not store the pre-filled pen with a needle attached.
- Discard the pen after last dose, even if it contains unused medicine.
- GENRYZON (Somatrogen) may be held at room temperature (up to 32 °C) for up to 4 hours with each injection for a maximum of 5 times. Return GENRYZON (Somatrogen) to the refrigerator again after each use.
- Do not leave at room temperature for more than 4 hours with each use.
- Do not put the pen anywhere that the temperature goes above 32 °C.
- If it has been more than 28 days after first use of your pen, get rid of it even if it contains unused medicine. If your pen or the pen of the child in your care has been exposed to temperatures higher than 32 °C, or has been removed from the refrigerator for more than 4 hours with each use or if it has been used a total of 5 times, get rid of it even if it contains unused medicine.

To help you remember when to dispose of your pen you can write the date of first use on the pen label.

A small amount of medicine may remain in the pen after all doses have been correctly given. Do not try to use any remaining medicine. After the last dose is given, the pen must be properly thrown away.

Do not throw away any medicines via wastewater or household waste. Ask your doctor 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 GENRYZON (Somatrogen) contains

- The active substance is somatrogen.

GENRYZON (Somatrogen) 24 mg solution for injection in pre-filled pen

One mL of solution contains 20 mg of somatrogen.

Each pre-filled pen contains 24 mg somatrogen in 1.2 mL of solution.

Each pre-filled pen delivers doses from 0.2 mg to 12 mg in a single injection in 0.2 mg increments.

GENRYZON (Somatrogen) 60 mg solution for injection in pre-filled pen

One mL of solution contains 50 mg of somatrogon.

Each pre-filled pen contains 60 mg somatrogon in 1.2 mL solution.

Each pre-filled pen delivers doses from 0.5 mg to 30 mg in a single injection in 0.5 mg increments.

- The other ingredients are: trisodium citrate dihydrate, citric acid monohydrate, L-Histidine, sodium chloride (see section 2 “GENRYZON (Somatrogon) contains sodium”), poloxamer 188, m-Cresol, water for injections.

What GENRYZON (Somatrogon) looks like and contents of the pack

GENRYZON (Somatrogon) is a clear and colourless to slightly light yellow solution for injection (injection) in a pre-filled pen.

GENRYZON (Somatrogon) 24 mg solution for injection is available in a pack size containing 1 pre-filled pen. The pen cap, dose button, and label on the pen are coloured lilac.

GENRYZON (Somatrogon) 60 mg solution for injection is available in a pack size containing 1 pre-filled pen. The pen cap, dose button, and label on the pen are coloured blue.

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