Strontium ranelate granules for oral suspension

1. What Strontium ranelate Aristo is and what it is used for

Strontium ranelate Aristo is a medicine used to treat severe osteoporosis (break bones), especially in your spine, hips and other part of your body, reducing bone breakdown and stimulating bone and making new bone tissue. If you have osteoporosis, your bone body breaks down more bone than it forms so that gradually bone loss occurs and your bones become thinner and fragile. This is especially common in women after the menopause. Many people with osteoporosis have no symptoms and you may not even know that you have it. However, osteoporosis makes you more likely to have fractures (break bones), especially in your spine, hips and wrists.

How Strontium ranelate Aristo works

Strontium ranelate Aristo contains the substance strontium ranelate, a group of medicines used to treat bone diseases. Strontium ranelate Aristo works by reducing bone breakdown and stimulating bone and reduces the risk of fracture. The newly formed bone is of normal quality.

2. What you need to know before you take Strontium ranelate Aristo

Do not take Strontium ranelate Aristo:

- if you are allergic to strontium ranelate or any of the other ingredients of this medicinal product (see section 4). Potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis and severe hypersensitivity reactions (DRESS)) have been reported in association with the use of strontium ranelate Aristo. The highest risk of occurrence of serious skin reactions is within the first weeks of treatment for Stevens-Johnson syndrome and toxic epidermal necrolysis and usually around 3-6 weeks for DRESS. If you develop a rash or serious skin symptoms (see section 4), stop taking Strontium ranelate Aristo, seek urgent advice from a doctor and tell him that you are taking this medicine.
- if you have established ischaemic heart disease (temporary reduction of blood flow to the brain; also known as “mini-stroke”), angina, or blockages of blood vessels to the heart or brain;
- if you have or have had blood problems with your blood circulation (peripheral artery disease) or if you have had surgery on the arteries of your legs;
- if you have high blood pressure not controlled by treatment.

3. How to take Strontium ranelate Aristo

The recommended dose is one 2 g sachet (to be completed nationally, e.g. “If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism)” talk to your doctor before taking Strontium ranelate Aristo as you may be at higher risk of skin reactions. Strontium ranelate Aristo is unlikely to affect your ability to drive or use machines. Strontium ranelate Aristo contains asparagine (E 951) (to be completed nationally, e.g. “If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism)” talk to your doctor before starting to take this medicine.

3. How to take Strontium ranelate Aristo

The treatment should only be started by a doctor with experience in treating osteoporosis. Always take this medicine exactly as your doctor or pharmacist has told you. The recommended dose is one 2 g sachet a day.

It is recommended that you take Strontium ranelate Aristo at bedtime, preferably...
at least 2 hours after dinner. You may lie down immediately after taking Strontium ranelate Aristo if you wish.

Method of administration
Take the granules contained in the sachets as a suspension in a glass containing a minimum of 30 ml (approximately one third of a standard glass) of water. See instructions below. Strontium ranelate Aristo can interact with milk and milk products, so it is important that you mix Strontium ranelate Aristo only with water to be sure it works properly.

Empty the granules from the sachet into a glass.

Add water.

Stir until the granules are evenly dispersed in the water.

Drink straight away. You should not leave more than 24 hours before you drink it. If for some reason you cannot drink the medicine straight away, make sure you stir it again before drinking.

Your doctor may advise you to take calcium and vitamin D supplements in addition to Strontium ranelate Aristo. Do not take calcium supplements at bedtime, at the same time as Strontium ranelate Aristo.

Your doctor will tell you how long you should continue to take Strontium ranelate Aristo. Osteoporosis therapy is usually required for a long period. It is important that you continue taking Strontium ranelate Aristo for as long as your doctor prescribes the medicine.

If you take more Strontium ranelate Aristo than you should
If you take more sachets of Strontium ranelate Aristo than recommended by your doctor or pharmacist. They may advise you to drink milk or take antacids to reduce the absorption of the active ingredient.

If you forget to take Strontium ranelate Aristo
Do not take a double dose to make up for forgotten individual doses. Just carry on with the next dose at the normal time.

If you stop taking Strontium ranelate Aristo
It is important that you continue taking Strontium ranelate Aristo for as long as your doctor prescribes the medicine. Strontium ranelate Aristo can treat your severe osteoporosis only if you continue to take it.

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.

If the following happens to you, stop using Strontium ranelate Aristo and talk to your doctor immediately:

Common: may affect up to 1 in 10 people
- Heart attack: sudden crushing pains in your chest which may reach your left arm, jaw, stomach, back and/or shoulders. Other symptoms may be nausea/vomiting, sweating, shortness of breath, palpitations, (extreme) tiredness and/or dizziness. Heart attack may occur commonly in patients at high risk for heart disease. Your doctor will not prescribe Strontium ranelate Aristo for you if you are at particular risk.
- Blood clots in veins: pain, redness, swelling in your leg, sudden chest pain or difficulty breathing.

Rare: may affect up to 1 in 1,000 people
- Signs of severe hypersensitivity reactions (DRESS) initially as flu-like symptoms and a rash on the face then an extended rash with a high temperature (uncommon), increased levels of liver enzymes seen in blood tests (uncommon) an increase in a type of white blood cell (eosinophilia) (rare) and enlarged lymph nodes (uncommon).

Very rare: may affect up to 1 in 10,000 people
- Signs of potentially life-threatening skin rashes (Stevens-Johnson syndrome, toxic epidermal necrolysis: initially as reddish target-like spots or circular patches often with central blisters on the skin. Additional signs may include ulcers in the mouth, throat, nose, genitalia and conjunctivitis (red and swollen eyes). These potentially life-threatening skin rashes are often accompanied by flu-like symptoms. The rash may progress to widespread blistering or peeling of the skin.

Other possible side effects
Very common: may affect more than 1 in 10 people
- Itching, hives, skin rash, angioedema (such as swollen face, tongue or throat, difficulty in breathing or swallowing), bone, limb and/or joint pain, muscle cramps.

Common: may affect up to 1 in 10 people
- Vomiting, abdominal pain, reflux, indigestion, constipation, flatulence, difficulty in sleeping, inflammation of the liver (hepatitis), swelling in limbs, bronchial hyperreactivity (symptoms include wheezing and shortness of breath and cough), increased level of a muscle enzyme (Creatine phosphokinase), increased levels of cholesterol, nausea, diarrhoea, headache, eczema, memory trouble, fainting fit, pins and needles, dizziness, vertigo.

However, these effects were mild and short lived and usually did not cause the patients to stop taking their treatment. Talk to your doctor if any effects become troublesome or persist.

Uncommon: may affect up to 1 in 100 people
- Seizures, oral irritation (such as mouth ulcers and gum inflammation), hair loss, feeling confused, feeling unwell, dry mouth, skin irritation.

Rare: may affect up to 1 in 1,000 people
- Reduction in production of blood cells in the bone marrow.
- If you have stopped treatment due to hypersensitivity reactions, do not take Strontium ranelate Aristo again.

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 for and look for MRHA Yellow Card in the Google Play or Apple store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Strontium ranelate Aristo
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 sachet after “EXP.”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. 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 Strontium ranelate Aristo 2 g granules for oral suspension contain
- The active substance is: Strontium ranelate. Each sachet with 4 g granules contains 2 g of strontium ranelate.
- The other ingredients are: mannitol (E 421), mc, maltodextrin, aminopterin (E 951), vanillin.

What Strontium ranelate Aristo looks like and contents of the pack
Strontium ranelate Aristo 2 g granules for oral suspension are available in sachets containing white to beige granules.

Strontium ranelate Aristo 2 g granules for oral suspension are supplied in bottles of 14, 28 or 84 sachets containing 4 g granules each.

Not all pack sizes may be marketed.

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Aristo Pharma GmbH
Wallenroder Straße 8-10
13435 Berlin
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Manufacturer
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This leaflet was last revised in December 2017.
Strontium ranelate

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.

How to store Strontium ranelate Aristo

Strontium ranelate Aristo is a medicine used to treat severe osteoporosis, and to prevent or reduce the risk of fractures in primary osteoporosis and primary osteoporosis with established vertebral fractures.

How to take Strontium ranelate Aristo

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

What is in this leaflet

Do not take Strontium ranelate Aristo if you are allergic to any of the ingredients of this medicine (listed in section 6).

Warnings and precautions

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

You can get the information you need by reading this leaflet and any other leaflets you are given, and by talking to your doctor or pharmacist.
at least 2 hours after dinner. You may lie down immediately after taking Strontium ranelate Aristo if you wish.

Method of administration
Take the granules contained in the sachets as a suspension in a glass containing a minimum of 30 ml (approximately one third of a standard glass) of water. See instructions below. Strontium ranelate Aristo can interact with milk and milk products, so it is important that you mix Strontium ranelate Aristo only with water to be sure it works properly.

1. Empty the granules from the sachet into a glass.
2. Add water.
3. Stir until the granules are evenly dispersed in the water.

Drink straight away. You should not leave more than 24 hours before you drink it. If for some reason you cannot drink the medicine straight away, make sure you stir it again before drinking.

Your doctor may advise you to take calcium and vitamin D supplements in addition to Strontium ranelate Aristo. Do not take calcium supplements at bedtime, at the same time as Strontium ranelate Aristo.

Your doctor will tell you how long you should continue to take Strontium ranelate Aristo. Osteoporosis-therapy is usually required for a long period. It is important that you continue taking Strontium ranelate Aristo for as long as your doctor prescribes the medicine.

If you take more Strontium ranelate Aristo than you should
If you take more sachets of Strontium ranelate Aristo than recommended by your doctor, tell your doctor or pharmacist. They may advise you to drink milk or take antacids to reduce the absorption of the active ingredient.

If you forget to take Strontium ranelate Aristo
Do not make up for missed doses. Take the next dose at the normal time.

If you stop taking Strontium ranelate Aristo
It is important that you continue taking Strontium ranelate Aristo for as long as your doctor prescribes the medicine. Strontium ranelate Aristo can treat your severe osteoporosis only if you continue to take it. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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- Blood clots in veins: pain, redness, swelling in your leg, sudden chest pain or difficulty breathing.
- Seizures, oral irritation (such as mouth ulcers and gum inflammation), hair loss, feeling confused, feeling unwell, dry mouth, skin irritation.
- Rash: may affect up to 1 in 1,000 people Reduction in production of blood cells in the bone marrow.
- If you have stopped treatment due to hypersensitivity reactions, do not take Strontium ranelate Aristo again.

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

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Do not throw away any medicines via wastewater. 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 Strontium ranelate Aristo 2 g granules for oral suspension contain - The active substance is: strontium ranelate. Each sachet with 4 g granules contains 2 g of strontium ranelate.
- The other ingredients are: mannitol (E 421), microcrystalline cellulose (E 901), magnesium stearate (E 460).* * You can help provide more information on the safety of this medicine.

What Strontium ranelate Aristo looks like and of the pack
Strontium ranelate Aristo 2 g granules for oral suspension are available in sachets containing white to beige granules.

Strontium ranelate Aristo 2 g granules for oral suspension are supplied in boxes of 14, 28 or 84 sachets containing 4 g granules each.

Not all pack sizes may be marketed.

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