

PATIENT INFORMATION LEAFLET
ACTAMAX RANGE

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

ACTAMAX 5 mg film coated tablet

ACTAMAX 35 mg film coated tablet

Read all of this leaflet carefully before you start taking ACTAMAX.

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

ACTAMAX has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT ACTAMAX CONTAINS:

The active substance is risedronate sodium.

ACTAMAX 5 mg: Each film coated tablet contains risedronate sodium hemipentahydrate equivalent to 5 mg risedronate sodium.

ACTAMAX 35 mg: Each film coated tablet contains risedronate sodium hemipentahydrate equivalent to 35 mg risedronate sodium.

The other ingredients are crospovidone, magnesium stearate, microcrystalline cellulose, Opadry white (consisting of hypromellose, lactose monohydrate, macrogol/PEG 4000, titanium dioxide), pregelatinised starch.

ACTAMAX 5 mg tablets contain sugar (lactose monohydrate 0,6 mg/tablet).

ACTAMAX 35 mg tablets contain sugar (lactose monohydrate 2,00 mg/tablet).

2. WHAT ACTAMAX IS USED FOR:

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ACTAMAX belongs to a group of medicines called bisphosphonates which are used to treat osteoporosis.

ACTAMAX is prescribed by medical practitioners to treat osteoporosis (thinning of the bone) in woman after menopause, in combination with calcium 500 – 1 000 mg per day. Your doctor will advise you, if in addition, you require vitamin D supplementation.

3. BEFORE YOU TAKE ACTAMAX:

Do not take ACTAMAX:

- if you are hypersensitive (allergic) to risedronate or to any of the other ingredients of **ACTAMAX** (see **WHAT ACTAMAX CONTAINS**)
- if you have been diagnosed with a condition called hypocalcaemia (deficiency of calcium in the blood)
- if you are suffering from severe kidney disease
- if you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with ACTAMAX:

- if you are a very elderly patient (over the age of 80)
- If you have or have previously had problems with your throat, for instance you may have or have had pain or difficulty in swallowing food.
- if you have a history of stomach ulcers or indigestion
- immediately stop taking **ACTAMAX** tablets if you develop symptoms of oesophageal disease (such as difficulty or pain upon swallowing, retrosternal pain (pain behind the breastbone) or new or worsening heartburn) and consult your doctor
- if you have abnormal bone and mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities, both leading to a low blood calcium level) as you may need to take additional calcium and vitamin D during treatment with **ACTAMAX**

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if you are unable to stay in an upright position (sitting or standing) for at least 30 minutes

- if you take any food, drinks or medicines containing calcium, magnesium, iron and aluminium (such as antacids for heartburn, nutritional supplements) as these may interfere with how **ACTAMAX** works. These products should not be taken at the same time as **ACTAMAX** (see **Taking other medicines with ACTAMAX**)
- **ACTAMAX** should be taken first thing in the morning at least 30 minutes before any food, drink or any other medicine other than water. Failing this, **ACTAMAX** should be taken two hours either before or after the intake of any medicine, food or liquid
- if you have had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth as your dentist will need to correct any of these problems before you start treatment with **ACTAMAX**
- if you are under dental treatment or need to undergo dental surgery, tell your dentist that you are being treated with **ACTAMAX**.

Your doctor may request tests to monitor your condition before and/or during treatment.

Taking ACTAMAX with food and drink:

ACTAMAX tablets must always be taken at least 30 minutes before the first food, drink or any other medicine of the day, other than water. If this is not possible, **ACTAMAX** should be taken at least two hours before or after the intake of food or drink during the course of the day.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ACTAMAX**.

DO NOT take **ACTAMAX** if you are pregnant, suspect you are pregnant or you are planning to become pregnant (see **Do not take ACTAMAX**).

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DO NOT take **ACTAMAX** if you are breastfeeding your baby (see **Do not take ACTAMAX**).

Driving and using machinery:

ACTAMAX should not have any effect on your ability to drive and use machinery. Do not operate machinery or drive a vehicle until you know how **ACTAMAX** affects you.

Important information about some of the ingredients of ACTAMAX:

ACTAMAX contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **ACTAMAX**.

ACTAMAX contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Taking other medicines with ACTAMAX:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Medicines containing calcium, magnesium, iron and aluminium, including antacids, mineral supplements and some certain laxatives may interfere with the absorption of **ACTAMAX** and should not be taken at the same time (see **Take special care ACTAMAX**).

4. HOW TO TAKE ACTAMAX:

Do not share medicines prescribed for you with any other person. Always take **ACTAMAX** exactly as your doctor has instructed you.

The dosage and dosage interval will be determined by your condition.

You should check with your doctor or pharmacist if you are unsure.

The usual dose is:

ACTAMAX 5 mg: one tablet every day.

ACTAMAX 35 mg: one tablet once a week on the same day of the week.

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ACTAMAX must always be taken at least 30 minutes before the first food, liquid or any other medicine of the day other than water, at least two hours before or after food or liquid at any other time of the day and at least 30 minutes before going to bed. **ACTAMAX** should not be taken at bedtime or before getting up in the morning. The tablets must be swallowed whole and not sucked or chewed. Food, beverages and medicines containing calcium, magnesium, iron and aluminium may interfere with the absorption of **ACTAMAX** and should not be taken at the same time.

You should take **ACTAMAX** while in an upright position with a glass of plain water (≥ 120 ml) to aid delivery to the stomach. You should not lie down for 30 minutes after taking the tablet (see **Take special care ACTAMAX**).

Take **ACTAMAX** preferably on arising in the morning.

If you have the impression that the effect of **ACTAMAX** is too strong or too weak, tell your doctor or pharmacist.

If you take more ACTAMAX than you should

In the event of an overdose, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of ACTAMAX:

ACTAMAX 5 mg:

If you miss a dose, take it as soon as you remember. Two tablets should not be taken on the same day.

Do not take a double dose to make up for forgotten individual doses.

ACTAMAX 35 mg:

If a dose is missed, one **ACTAMAX** tablet should be taken on the day that the tablet is

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remembered.

Patients should then return to taking one tablet once a week on the day the tablet is normally taken. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with ACTAMAX is stopped:

It is important that you continue the course of treatment. Do not stop taking **ACTAMAX** unless your doctor tells you to do so.

5. POSSIBLE SIDE EFFECTS:

ACTAMAX can have side effects. Not all side effects reported for **ACTAMAX** are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking **ACTAMAX** please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ACTAMAX** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ACTAMAX**. You may need urgent medical attention or hospitalisation

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- bruising easily (thrombocytopenia)
- weakness, fatigue, weight loss, headache (symptoms of a condition called vasculitis)
- Stevens-Johnson syndrome (a life threatening skin disorder with symptoms such as a red-purplish rash and blisters)

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- severe bone, joint or muscle pain
- thigh or groin pain (which may be a side effect of a bone fracture)
- swelling in any part of the body.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- indigestion, nausea, vomiting, abdominal pain, diarrhoea, constipation, abdominal pain, gastritis
- dry eyes, eye pain and inflammation, conjunctivitis (pink eye)
- headache.

Less frequent side effects:

- pain, swelling, redness, or other signs of infection in the gums or sockets that don't heal after dental work
- anaemia, abnormal blood test results
- inflammation (swelling), narrowing or ulcer of the oesophagus (tube that goes to the stomach with symptoms such as difficulty or pain when swallowing), swelling of the tongue
- blurred vision, abnormal vision, vision disturbances
- abnormal liver function test results
- skin rashes or other skin conditions, such as flushing, hives, itching, dry skin, and hair-loss to serious skin conditions causing blisters and peeling, tissue damage
- fever, chills
- general feeling of discomfort or being unwell.

6. STORING AND DISPOSING OF ACTAMAX:

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Store at or below 25 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use the tablets after the expiry date printed on the carton.

Do not remove a tablet from the outer carton until you are ready to take the dose.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).