Read all of this leaflet carefully before you start taking this medicine because it contains important information about your treatment. Keep this leaflet. You may need to read it again.

If you have any questions about Actonel or if you want more information, talk to your doctor or pharmacist.

This leaflet does not replace the information your doctor or pharmacist has prescribed for you. Do not pass it on to others. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

While taking Actonel, tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

Actonel is not known to affect your ability to drive or use machines.

If you have any side effects that you think might be due to Actonel, talk to your doctor or pharmacist.

Take the tablet with the water on an empty stomach (you may feel a slight burn) to avoid heartburn. Do not chew it.

If you forget to take Actonel

Do not take a double dose to make up for a forgotten tablet. Do not take more tablets than the one your doctor or pharmacist has prescribed for you.

If you stop taking Actonel

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

Bone loss decreases simply because you are not gaining as much bone as you are losing. Bone loss may occur in women after the menopause or in men with osteoporosis.

The treatment of osteoporosis

Many patients with osteoporosis have no symptoms at first. Osteoporosis-related fractures can also occur in women after the menopause where the bones become weaker, more fragile and more likely to break.

Risedronate sodium is not recommended for use in children and adolescents taking Actonel if you have any of the above.

If you have or have had problems in the past with changes in the cells that line the lower oesophagus (the tube that connects your mouth to your stomach), take the tablet with plain water (other than plain water) for 2 hours after taking the tablet.

You may feel a slight burn, but this only occurs in very few people. If you experience any pain, swelling or loosening of a tooth.

Tell your doctor promptly if you have any of the following:

Tell your doctor promptly if you have any of the following:

Severe pain, swelling or loosening of a tooth.

•  If you are having dental treatment or will undergo dental treatment

•  If you are under dental treatment or will undergo dental treatment

•  If you have had or have pain, swelling or loosening of a tooth.

•  If you have or have had pain, swelling or loosening of a tooth.

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

•  If you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Actonel"). The potential risk associated with the use of risedronate sodium is unknown.

If you have or have had any of the above:

•  Severe skin reactions that can include blistering of the skin, peeling of the skin, swelling of the mouth, throat, lips, tongue, eyes or face, or trouble breathing

•  Severe skin reactions that can include blistering of the skin, peeling of the skin, swelling of the mouth, throat, lips, tongue, eyes or face, or trouble breathing

•  If you stop taking Actonel

•  Do not lie down for 30 minutes after taking your tablet.

•  Do not take a double dose to make up for a forgotten tablet

•  Do not take more tablets than the one your doctor or pharmacist has prescribed for you

•  If you have any side effects that you think might be due to Actonel, talk to your doctor or pharmacist

•  Do not take Actonel

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

•  If you have had or have pain, swelling or loosening of a tooth.

You must not take Actonel:

•  Do not take Actonel with food and drink

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

•  If you forget to take Actonel

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

Actonel is not recommended for use in children and adolescents.

You may feel a slight burn, but this only occurs in very few people. If you experience pain, swelling or loosening of a tooth.

The treatment of osteoporosis

Many patients with osteoporosis have no symptoms at first. Osteoporosis-related fractures can also occur in women after the menopause where the bones become weaker, more fragile and more likely to break.

Risedronate sodium is not recommended for use in children and adolescents.

Another condition called hypocalcaemia (a low blood calcium level) may occur in very few people.

Take food and drinks (other than plain water) at least 30 minutes after your Actonel tablet.

Take food and drinks (other than plain water) at least 30 minutes after your Actonel tablet.

If in particular instance you are unable to take your Actonel tablet at this time, you may take it on an empty stomach (you may feel a slight burn) to avoid heartburn. Do not chew it.

If you forget to take Actonel

Tell your doctor promptly if you have any of the following:

•  If you take more Actonel than you should

•  If you stop taking Actonel

Do not take Actonel tablet with food and drink:

•  If you may be pregnant, are pregnant or planning to become pregnant

•  If you have or have had problems in the past with changes in the cells that line the lower oesophagus (the tube that connects your mouth to your stomach)

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

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

•  If you happen to break after a fall or strain.

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

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

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

Tell your doctor promptly if you have any of the following:

•  Severe skin reactions that can include blistering of the skin, peeling of the skin, swelling of the mouth, throat, lips, tongue, eyes or face, or trouble breathing

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Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

•  Do not lie down for 30 minutes after taking your tablet.

•  Do not take Actonel if you are under dental treatment or will undergo dental treatment

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

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

Tell your doctor or pharmacist if you are pregnant or planning to become pregnant.

•  Do not lie down for 30 minutes after taking your tablet.

•  Do not take Actonel if you are under dental treatment or will undergo dental treatment

•  If you may be pregnant, are pregnant or planning to become pregnant

•  If you have or have had problems in the past with changes in the cells that line the lower oesophagus (the tube that connects your mouth to your stomach)

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•  If you receive a allergy to risedronate sodium or any of the other ingredients of Actonel film-coated tablets

•  If you are taking, have taken or are going to take medicines called non-steroidal anti-inflammatory drugs (NSAIDs) or diuretics.

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Risedronic Acid (Actonel) 5mg Film-coated Tablets PIL - UK/IE

1. What this medicine is and why you are taking it

Risedronic Acid (Actonel) is used to treat osteoporosis, a condition that weakens bones and increases the risk of breaking them. It is also used to prevent bone loss after spinal surgery.

2. How to take this medicine

- The active substance is risedronate sodium. Each tablet contains 5 mg risedronate sodium, equivalent to 4.64 mg risedronic acid.
- The tablets are supplied in blister packs of 14, 28 (2x14), 84 (6x14), 98 (7x14) tablets. Not all pack sizes may be marketed.

3. How to take this medicine

- Swallow the tablets whole with a full glass of water (at least 250 ml) and take 30 minutes before you start eating your breakfast.
- Do not take the tablets with milk or food.
- Do not drink carbonated drinks immediately before or after taking the tablets.
- The tablets should be taken once a week, usually on Sundays at 12 am.

4. Possible side effects

- Common side effects: Nausea, vomiting, and indigestion.
- Rare side effects: Changes in the shape of the jaw.
- Very rare side effects: Inflammation of the ear.

5. How to store Actonel

- Keep the medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which can only be diagnosed from a blood test.
- Very rare (may occur at up to 1 in 10,000 people):
  - Stiffness of your neck and muscle pain, especially while lying down, and on waking in the morning.
  - Abnormal liver tests have been reported. These can only be diagnosed from a blood test.

6. Contents of the pack and other information

- The active substance is risedronate sodium. Each tablet contains 5 mg risedronate sodium, equivalent to 4.64 mg risedronic acid.
- The other ingredients are:
  - Dibasic calcium phosphate (5%), microcrystalline cellulose, magnesium stearate, and colloidal anhydrous silica.
  - Lactose, hydroxypropylcellulose, colloidal anhydrous silica, colloidal anhydrous silica, talc, and isopropyl alcohol.

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