package leaflet: information for the patient

Risedronate Sodium Accord Once a Week 35 mg

35 mg

oral tablets

Read all of the leaflet before you start treatment. This leaflet contains important information for you.

If you have any other questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their age is the same as yours.

For young people/adolescents

This includes any possible side effects not listed in this leaflet. See section 4, "Possible side effects".

Risedronate Sodium Accord Once a Week and what it is used for

Risedronate Sodium Accord Once a Week is used to treat bone diseases.

The spine, hip and wrist are the most likely bones to become weaker, more fragile and more likely to break.

Bisphosphonates which are used to treat bone diseases.

The recommended dose is ONE Risedronate Sodium Accord Once a Week tablet. Also, write in the dates you choose to take your Risedronate Sodium Accord Once a Week.

For your convenience, so that you take your tablet at the same time every week. This is very important, so that you take the tablets properly.

Children and adolescents

Risedronate Sodium Accord Once a Week is recommended for use in children below 18 due to insufficient data on safety and efficacy.

Some medicines may affect the way Risedronate Sodium Accord Once a Week works, or this medicine may affect the way other medicines work.

In particular do not take this medicine or the same time as any iron products (such as in tablets or other medicine). See section 2, "Do not take with other medicines or stop taking other medicines without telling your doctor or pharmacist".

You may not even have known that you had it.

The spine, hip and wrist are the most likely bones to break after a fall or strain.

Your doctor will advise you on what to do when taking Risedronate Sodium Accord Once a Week if you:

• If you have had or have pain, swelling or redness of the jaw or if "tooth problems" become visible or develop in your jaw.

• If you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Pregnancy and breast-feeding").

• If you have severe kidney problems.

• If you get any side effects, talk to your doctor or pharmacist.

Do not take a double dose to make up for a missed dose. Return to taking one tablet once a week on your chosen day, take it on the day you remember.

Do not take Risedronate Sodium Accord Once a Week if:

• You are allergic to risedronate sodium or any of the other ingredients of this medicine (see section 2, "What other medicines and Risedronate Sodium Accord Once a Week may affect"

• You are pregnant or planning to become pregnant.

• If you are breastfeeding.

• If you have severe kidney problems.

• If you have any unusual bleeding or bruising.

• If you have bleeding problems (including easy bruising or nosebleeds). Talk to your doctor or pharmacist before you start taking Risedronate Sodium Accord Once a Week.

• If you have or have had or are likely to have problems in the past with swallowing tablets or taking tablets with milk or other food.

• If you have been told by your doctor that you have rheumatoid arthritis (a type of arthritis characterized by joint swelling and pain).

• If you are taking other medicines or stop taking other medicines without telling your doctor or pharmacist. See section 2, "Other medicines and Risedronate Sodium Accord Once a Week"

• If you get any side effects on this medicine, ask your doctor or pharmacist.

If you stop taking Risedronate Sodium Accord Once a Week, please talk to your doctor or pharmacist before you consider taking other medicines.

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

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Children and adolescents

Risedronate Sodium Accord Once a Week is recommended for use in children below 18 due to insufficient data on safety and efficacy.

Other medicines and Risedronate Sodium Accord Once a Week

Medicines containing one of the following have been shown to reduce the effectiveness of Risedronate Sodium Accord Once a Week if taken at the same time:

• iron

• magnesium

• vitamins

(For example some indigestion remedies)

Take these medicines at least 30 minutes after your Risedronate Sodium Accord Once a Week tablet. Also, write in the dates you choose to take your Risedronate Sodium Accord Once a Week.

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4. Possible side effects
Use all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Risedronic Sodium Accord Once a Week and contact a doctor immediately if you experience any of the following:

- Symptoms of a severe allergic reaction such as:
  - Swelling of face, tongue or throat
  - Difficulty in swallowing
  - Hives and difficulty in breathing

- Severe skin reactions that can include blistering of the skin

If you experience the following side effect:

- Pain, redness and light sensitivity

- Rare reactions of the skin (hives), associated with delayed feeling and itching, after further contact

- Vision changes (see section 2, “Warning and precautions”)

- Changes to your bowels, including bloody diarrhoea, dark blood in your stools, pain in your lower abdomen

Rare side effects may affect up to 1 in 1,000 people

- Inflammation of the tongue (tongue swelling, possibly painful), narrowing of the oesophagus (the tube that connects your mouth with your stomach)

- Inflammation or ulcer of the oesophagus (the tube that connects your mouth with your stomach)

- Indigestion, feeling sick, stomach ache, stomach pain, bloating, fullness, diarrhea

- Pain in your bones, muscles or joints

- Hair loss

- Swelling of face, tongue or throat

- Eye inflammation, usually with pain, redness and light sensitivity

- Rare side effects may affect up to 1 in 10,000 people

- Pain in your lower abdomen

- Swelling of the skin

- Light sensitivity

5. How to store Risedronic Sodium Accord Once a Week

- 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 and blister after EXP. The expiry date refers to the last day of that month.

- This medicine does not require any special storage conditions.

- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures help protect the environment.

6. Contents of the pack and other information

- What Risedronic Sodium Accord Once a Week looks like and contents of the pack

- Risedronic Sodium Accord Once a Week 35 mg tableted tablets

- This leaflet was last revised in March 2020

- Risedronic Acid 35mg Tablets PIL - UK/IE

- Approved for print/date

- Pr of proof Round Technical

- Date sent:

- Date received:

- Item...

- 7

- 12.02.2020

- Cartons and label leaflets only

- (labels only when specified) German GTIN 14

- (incorporating PZN): 

- BBBA7750

- Version 7

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- T. Hull

- Date sent: 11.03.2020

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- EU-Artwork-Support@accord-healthcare.com

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