1. WHAT BINOSTO IS AND WHAT IT IS USED FOR

What is Binosto?
Binosto is a once weekly treatment. Binosto reduces the risk of spine and hip fractures.

What is osteoporosis?
Osteoporosis is a thinning and weakening of the bones. It is common in women after the menopause. At the menopause, the oestrogen that protects the body’s skeleton diminishes. As a result, bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

How can osteoporosis be treated?
Osteoporosis can be treated and it is never too late to begin treatment. Binosto not only prevents the loss of bone but actually helps to re-build bone and reduces the risk of bones breaking in the spine and hip and other places.

As well as your treatment with Binosto, your doctor may suggest you make changes to your lifestyle to help your condition, such as:
• Smoking: smoking appears to increase the rate at which you lose bone and, therefore, may increase your risk of broken bones.
• Exercise: like muscles, bones need exercise to stay strong and healthy. Consult your doctor before you begin any exercise programme.
• Eating a balanced diet: your doctor can advise you about your diet or whether you should take any dietary supplements (especially calcium and Vitamin D).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BINOSTO

Do not take Binosto
1. If you are allergic (hypersensitive) to alendronate or any of the other ingredients of this medicine (listed in section 6).
2. If you have certain problems with your gullet (oesophagus – the tube that connects your mouth with your stomach) often with difficulty swallowing.
3. If you cannot stand or sit upright for at least 30 minutes.
4. If you have any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
• What Binosto is and what it is used for
• What you need to know before you take Binosto
• How to take Binosto
• Possible side effects
• How to store Binosto
• Contents of the pack and other information

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist or nurse.
• This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
• If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Binosto should not be given to children and adolescents.

Other medicines and Binosto
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. If it is likely that calcium supplements, analgesics, and some oral medicines will interfere with the absorption of alendronate if taken at the same time, then, it is important that you follow the advice given in section 3. HOW TO TAKE BINOSTO.

Binosto with food and drink
It is likely that food and beverages (including mineral water) will make Binosto less effective if taken at the same time. Therefore, it is important that you follow the advice given in section 3. HOW TO TAKE BINOSTO.

Pregnancy, breast-feeding and fertility
Binosto is only intended for use in postmenopausal women. You should not take Binosto if you are or think you may be pregnant, or if you are breast-feeding.

Driving and using machines
There have been side effects (including blurred vision, dizziness and severe bone, muscle or joint pain) reported with alendronate which may affect your ability to drive or operate machinery. Individual responses to alendronate may vary (see section 4. POSSIBLE SIDE EFFECTS). Binosto contains sodium This medicinal product contains 26.2 mmol (or 600.54 mg) sodium per dose. This should be taken into consideration by patients on a controlled sodium diet.

3. HOW TO TAKE BINOSTO

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

Binosto must be dissolved in half a glass of plain water before taking. Do not chew or swallow the tablet whole.

Take one Binosto effervescent tablet once a week, as an oral solution.

Follow these instructions carefully to make sure you will benefit from Binosto.

1. Choose the day of the week that best fits your schedule. Every week, take one Binosto effervescent tablet as an oral solution on your chosen day.

It is very important to follow instructions 2., 3., 4. and 5. to help the Binosto effervescent tablet as an oral solution, reach your stomach quickly and help reduce the chance of irritating your gullet (oesophagus – the tube that connects your mouth with your stomach).

2. After getting up for the day and before taking any food, drink, or other medicine, dissolve your Binosto effervescent tablet in half a glass of plain water (not less than 120 ml or 4.2 fl oz) (not mineral water). Once the fizzing has subsided and the effervescent tablet has completely dissolved to give a clear, slightly cloudy solution, drink this solution, followed by at least 30 ml (one sixth of a glass) of plain water. You may take additional water.

In case you perceive any undissolved tablet material at the bottom of the glass, you may stir the solution until it is dissolved.

- Do not take with mineral water (still or sparkling).
- Do not take with coffee or tea.
- Do not take with juice or milk.

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It is important that you continue taking Binosto for as long as your doctor prescribes the medicine. Binosto can treat your osteoporosis only if you continue to take the effervescent tablets dissolved in plain water. If you have any further queries on the use of this medicine, ask your doctor or pharmacist.

DO NOT SWALLOW THE UNDISsovLED EFFERVESCENT TABLET OR CHEW THE EFFERVESCENT TABLET OR ALLOW IT TO DISSOLVE IN YOUR MOUTH.

1. This medicinal product is authorized in the Member States of the EEA under the following names:
   - DE Binosto® 70 mg Brausetabletten
   - EL Binosto® 70 mg Αλενδρονατόν (αλενδρόνατον)
   - ES Binosto® 70 mg comprimidos efervescentes
   - FR Steénfort® 70 mg comprimé effervescent
   - IE Binosto® Once Weekly 70 mg Effervescent Tablets
   - IT Binosto® 70 mg Compresse effervescenti
   - PT Binosto® 70 mg Comprimidos efervescentes
   - DE Binosto® 70 mg Brausetabletten
   - LN Binosto® 70 mg efervescentefrade
   - MK Binosto® 70 mg komprimi efervescent
   - RO Binosto® 70 mg Comprimate efervescent
   - UK Binosto® 70 mg Efervescent Tablets

   This leaflet was last revised in January 2017.

2. Do not take Binosto at bedtime or before getting up for the day.

3. Do not lie down – stay fully upright (sitting, standing or walking) – for at least 30 minutes before drinking the oral solution containing the dissolved effervescent tablet. Do not lie down until after your first food of the day.

4. Do not take Binosto at bedtime or before getting up for the day.

5. If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking Binosto and contact your doctor.

6. After drinking the oral solution containing the dissolved Binosto effervescent tablet, wait at least 30 minutes before taking your first food, drink, or other medicine of the day, including antacids, calcium supplements and vitamins. Binosto is effective only if taken when your stomach is empty.

7. If you take more Binosto than you should If you take too many effervescent tablets by mistake, drink a full glass of milk and contact your doctor immediately.

8. Do not make yourself vomit, and do not lie down.

9. If you forget to take Binosto If you miss a dose, just take one effervescent tablet dissolved in plain water on the morning after you remember, following the aforementioned instructions 2., 3., 4., 5. and 6. Do not take two effervescent tablets for oral solution on the same day. Return to taking one effervescent tablet for oral solution once a week, as originally scheduled on your chosen day.

10. If you stop taking Binosto It is important that you continue taking Binosto for as long as your doctor prescribes the medicine. Binosto can treat your osteoporosis only if you continue to take the effervescent tablets dissolved in plain water. If you have any further queries on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

11. All medicines can cause allergic reactions, although serious allergic reactions are very rare. You should stop taking Binosto and tell your doctor immediately if you get any of the following symptoms:

- Sudden wheeziness, difficulty in breathing, swelling of the eyes, lids, face, throat, tongue, lips, rash or itching (especiticating your whole body)
- A rash made worse by sunlight; blistering or other effects on the skin; eyes, mouth or genitals; itching or high temperature (syptoms of severe skin reactions called Stevens-Johnson syndrome or toxic epidermal necrolysis)

12. If you have difficulty and/or pain when swallowing, you feel pain behind the breastbone or new or worsened heartburn, stop taking Binosto and contact your doctor. If you ignore these symptoms and continue to take your effervescent tablet, as an oral solution it is likely that these gullet reactions may get worse.

13. The following side effects have been reported:

   - Very Common (may affect more than 1 in 10 people):
     - Headache
     - Dizziness
     - Tiredness; swelling in the hands or legs

   - Common (may affect up to 1 in 10 people):
     - Headache; difficulty swallowing; pain upon swallowing; ulceration of the gullet (oesophagus – the tube that connects your mouth with your stomach) which can cause chest pain, heartburn or difficulty or pain upon swallowing
     - Joint swelling
     - Abdominal pain; uncomfortable feeling in the stomach or belching after eating; constipation; full or bloated feeling in the stomach; diarrhoea; flatulence
     - Hair loss; itching
     - Heartburn; diarrhoea
     - Nausea; vomiting
     - Rash; redness of the skin
     - Transient flu-like symptoms, such as aching muscles, generally feeling unwell and sometimes with fever usually at the start of treatment
     - Taste disturbance

   - Rare (may affect up to 1 in 100 people):
     - Allergic reactions such as hives, swelling of the face, lips, tongue and/or throat, possibly causing difficulty breathing or swallowing
     - Symptoms of low blood calcium levels including muscle cramps or spasms and/or tingling sensation in the fingers or around the jaw
     - Stomach or patic ulcers (sometimes severe or with bleeding)
     - Narrowing of the gullet (oesophagus – the tube that connects your mouth with your stomach)
     - Rash made worse by sunlight; severe skin reactions
     - Pain in the mouth, and/or jaw, swelling or sores inside the mouth, numbness or a feeling of heaviness in the jaw, or looseness of a tooth. These could be signs of bone damage in the jaw (osteonecrosis) generally associated with delayed healing and infection, often following tooth extraction. Contact your doctor and dentist if you experience such symptoms.
     - Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone
     - Mouth ulcers when the tablets have been chewed or sucked

   - Very Rare (may affect up to 1 in 10,000 people):
     - Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear

   - Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

   - It will help if you make a note of what you experienced, when it started and how long it lasted.

14. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly by the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Binosto contains

The active substance is: Alendronate sodium trihydrate

Each effervescent tablet contains 70 mg alendronic acid as 91.37 mg of alendronate sodium trihydrate.

The other ingredients are:

- Sodium hydrogen carbonate, citric acid anhydrous, sodium hydrogen carbonate, sodium carbonate anhydrous, strawberry flavour (maltodextrin (maize), arabic gum, propylene glycol (E 1520), nature-identical flavouring substances), ascorbic acid, potassium, sucrose.

What Binosto looks like and contents of the pack Binosto is available as round, white to off-white, flat facad effervescent tablets of 25 mm diameter and with bevelled edges. After dissolution of the tablet the solution is clear to slightly cloudy.

The effervescent tablets are supplied in strips of composite foil. Each strip contains 2 effervescent tablets packed in individual units. The strips are packed in cartons in pack sizes of 4, 12 or 24 effervescent tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Intasmine Pharmaceuticals Ltd

Linthwaite

Huddersfield

HD7 5QK, UK.

Manufacturer

Temmler Pharma GmbH

Temmlerstrasse 2

35359 Marburg

Germany

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