

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using JUBBONTI?

JUBBONTI contains the active ingredient denosumab. JUBBONTI is used to improve bone density and to reduce your risk of fracture. It is used to treat bone loss in women with osteoporosis after the menopause, men with osteoporosis, and men with prostate cancer who have reduced testosterone level caused by surgery or treatment with drugs. It is also used to improve bone density in patients treated with corticosteroids.

For more information, see Section [1. Why am I using JUBBONTI?](#) in the full CMI.

### 2. What should I know before I receive JUBBONTI?

Do not use if you have ever had an allergic reaction to denosumab, medicines using Chinese Hamster Ovary cells or any of the ingredients listed at the end of the CMI.

Do not use in patients under 18 years of age.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

**Tell your doctor if you have calcium deficiency.**

For more information, see Section [2. What should I know before I use JUBBONTI?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with JUBBONTI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How will I be given JUBBONTI?

The recommended dose of JUBBONTI is 60 mg given once every 6 months as a single injection under the skin.

More instructions can be found in Section [4. How do I use JUBBONTI?](#) in the full CMI.

### 5. What should I know while using JUBBONTI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using JUBBONTI.</li><li>• Take calcium and vitamin D supplements if your doctor has told you to.</li><li>• Maintain good oral hygiene when being treated with JUBBONTI.</li><li>• Attend all of your treatment and doctor's appointments so that your progress can be checked.</li><li>• Tell your doctor immediately if you become pregnant while taking JUBBONTI.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using JUBBONTI without talking to your doctor.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store JUBBONTI in the refrigerator (2°C to 8°C) in the original pack to protect from light. Do not freeze.</li><li>• Do not shake the pre-filled syringe.</li></ul>

For more information, see Section [5. What should I know while using JUBBONTI?](#) in the full CMI.

### 6. Are there any side effects?

Side effects that require urgent medical attention include: signs of an allergic reaction; muscle aches, twitches or cramps; numbness or tingling in your fingers, toes or around your mouth; persistent pain or swelling and/or non-healing sores in your mouth or jaw; pain in your hip, groin, or thigh, which is sometimes severe; severe allergic reaction with skin rash, blisters or fever.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# JUBBONTI®

Active ingredient(s): *denosumab (den"-os"-u"mab)*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using JUBBONTI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using JUBBONTI.**

Where to find information in this leaflet:

- [1. Why am I using JUBBONTI?](#)
- [2. What should I know before I receive JUBBONTI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given JUBBONTI?](#)
- [5. What should I know while using JUBBONTI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using JUBBONTI?

**JUBBONTI contains the active ingredient denosumab.** Denosumab is a protein (monoclonal antibody) that attaches (binds) specifically to another unique protein in the body in order to stop the development of bone-removing cells before they reach the bones and cause damage. Treatment with JUBBONTI makes your bone stronger and less likely to break.

**JUBBONTI is used to:**

- Treat osteoporosis in women after the menopause, to reduce the risk of spinal, non-spinal and hip fractures.
- Treat bone loss in men with osteoporosis at increased risk of fracture.
- Treat bone loss that results from a reduction in testosterone level caused by surgery or treatment with drugs in men with prostate cancer.
- Improve bone density in patients treated with corticosteroids.

Bone is a living tissue and is renewed all the time. In women, the ovaries produce the hormone oestrogen which helps keep bones healthy. After menopause, the oestrogen level drops which affects the bone renewal cycle so that more bone is lost than made, resulting in a lower bone mass. This leaves bones thin and fragile.

Osteoporosis is the term used to describe an increased fracture risk, usually with low bone density. Osteoporosis becomes more common with increasing age. It is more common in women. It can also occur in patients receiving corticosteroids. Many people with osteoporosis have no symptoms but they are still at risk of breaking bones (developing fractures), especially in the spine, hips and wrists.

Other things that can increase the risk of fractures include:

- age
- existence of a previous fracture
- family history of hip fractures
- low body weight
- drinking alcohol
- smoking.

JUBBONTI is prescribed to improve your body density and to reduce your risk of fracture.

Surgery or medicines used in the treatment of men with prostate cancer to stop the production of testosterone can also lead to bone loss. The bones become weaker and break more easily.

Your doctor, however, may have prescribed JUBBONTI for another reason.

## 2. What should I know before I receive JUBBONTI?

### Warnings

**Do not use JUBBONTI if:**

- you have low calcium levels in your blood (hypocalcaemia). Your doctor may do a blood test to check your calcium levels before you use JUBBONTI.
- you are pregnant, think you may be pregnant, or trying to get pregnant. JUBBONTI may harm your unborn baby.
- you are breast-feeding. It is not known if the active ingredient, denosumab, passes into breast milk.
- you are allergic to denosumab, any medicines that are produced using Chinese Hamster Ovary cells, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are a child or adolescent. JUBBONTI is not indicated for use in patients under 18 years of age.
- you are taking another medicine containing denosumab.
- the expiry date [EXP.] printed on the pack has passed. If you use it after the expiry date has passed, it may not work as well.
- the packaging is torn or shows signs of tampering.
- the JUBBONTI solution is cloudy or contains visible particles.

**Check with your doctor if you:**

- have allergies to any other medicines, or any other substances such as foods, preservatives or dyes.
- have calcium or vitamin D deficiency. If you are prone to low calcium levels, your doctor will monitor your blood especially in the first few weeks after starting

JUBBONTI. Severe low blood calcium levels may lead to hospitalisation, life-threatening events and death.

- are unable to take daily calcium or vitamin D supplements.
- have or have had severe kidney problems, kidney failure or have needed dialysis, which may increase your chance of getting low blood calcium if you do not take calcium supplements.
- had or have pain in the teeth, gums or jaw, swelling or numbness of the jaw, a "heavy jaw feeling" or loosening of a tooth. A dental condition called jaw osteonecrosis has been rarely reported in patients treated with denosumab. Your doctor should examine your mouth and may ask for a dental examination before you start JUBBONTI. You may need to have dental treatment completed before starting your medicine. You may have higher risk of developing jaw problems if you:
  - are undergoing chemotherapy, taking steroids, or are having a dental procedure
  - do not receive routine dental care, have gum disease or have taken JUBBONTI for a long time
- have been told by a doctor or other healthcare professional that you have an intolerance to some sugars.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

JUBBONTI has not been tested in pregnant women. Do not use JUBBONTI if you are pregnant, think you may be pregnant, or trying to get pregnant. JUBBONTI may harm your unborn baby.

Do not use JUBBONTI if you are breast-feeding. It is not known if the active ingredient, denosumab, passes into breast milk. It is important to talk to your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding or whether to stop taking JUBBONTI.

### Use in Children

Do not use JUBBONTI in children or adolescents under 18 years of age.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor if you are taking another medicine containing denosumab. If you are taking another denosumab-containing medication, you should not take JUBBONTI.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect JUBBONTI.**

## 4. How will I be given JUBBONTI?

### How is JUBBONTI given

- JUBBONTI is given as an injection under the skin. This is called a subcutaneous injection.

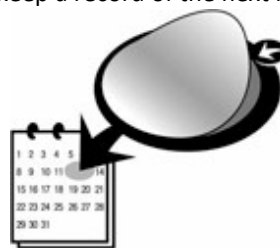
### How much JUBBONTI will I be given

- For each dose of JUBBONTI you will be given 60 mg as a single injection.

### When you will be given JUBBONTI

- JUBBONTI is injected once every 6 months.
- It is important to take your dose of JUBBONTI on schedule. Do not skip or delay getting your injection.

Each pack of JUBBONTI contains a calendar card with a sticker that can be removed from the carton. Use the peel-off stickers to mark the next injection date on your personal calendar and/or the calendar card be used to keep a record of the next injection date.



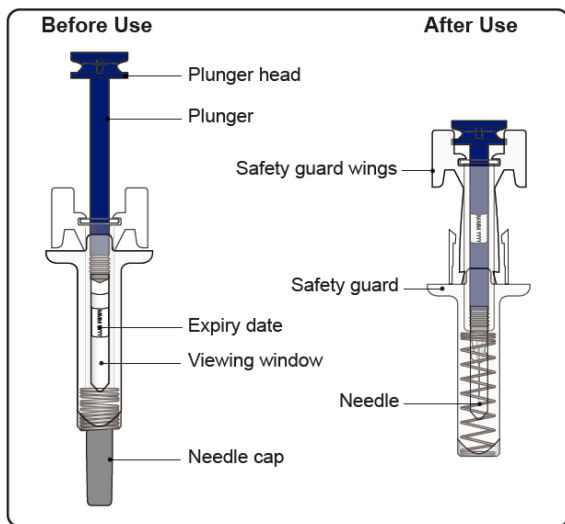
- Continue using JUBBONTI for as long as your doctor tells you to. JUBBONTI can treat osteoporosis and bone loss only for as long as you keep having treatment. Please talk to your doctor before you consider stopping treatment.
- You should also take calcium and vitamin D supplements while receiving JUBBONTI. JUBBONTI may lower the calcium levels in your blood. Your doctor, nurse or pharmacist will discuss how much calcium and vitamin D you should take to help prevent low calcium levels.

### Instructions for Use

These "Instructions for Use" contain information on how to inject JUBBONTI.

If your doctor decides that you or your caregiver may be able to give your injections of JUBBONTI at home, ensure that your doctor or nurse shows you or your caregiver how to prepare and inject with the JUBBONTI pre-filled syringe before you use it for the first time.

Be sure that you read and understand these Instructions for Use before injecting with the JUBBONTI pre-filled syringe. Talk to your doctor if you have any questions.



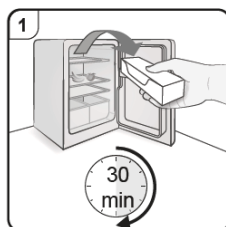
### Important information you need to know before injecting JUBBONTI

- JUBBONTI is for subcutaneous injection only (inject directly into fatty layer under the skin).
- **Do not** use the pre-filled syringe if any of the safety seals on the outer carton or the seal of the plastic tray is broken.
- **Do not** shake the pre-filled syringe at any time.
- **Do not** use if the pre-filled syringe has been dropped onto a hard surface or dropped after removing the needle cap.
- The pre-filled syringe has a safety guard that activates to cover the needle after the injection is finished. The safety guard helps to prevent needle stick injuries to anyone who handles the pre-filled syringe after injection.
- **Be careful not to touch the safety guard wings** before use. Touching them may cause the safety guard to activate too early.
- **Do not** attempt to re-use or disassemble the pre-filled syringe.
- **Do not** pull back on the plunger.

### Prepare to inject JUBBONTI

#### Step 1: Bring to room temperature

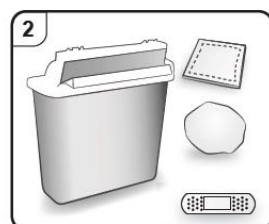
Take the carton containing the pre-filled syringe out of the refrigerator and leave it unopened for about 15 to 30 minutes so that it reaches room temperature.



#### Step 2: Gather supplies

Ensure that you have the following (not included in the carton):

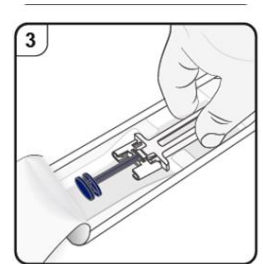
- Alcohol wipe
- Cotton ball or gauze pad
- Sharps disposal container
- Adhesive plaster



#### Step 3: Unpack

Open the plastic tray by peeling away the cover. Remove the pre-filled syringe by holding it in the middle as shown.

**Do not** remove the needle cap until you are ready to inject.



#### Step 4: Perform safety checks

Look through the viewing window of the pre-filled syringe. The liquid inside should be a clear, colourless to slightly yellowish or slightly brownish solution. You may see air bubbles in the liquid, which is normal.

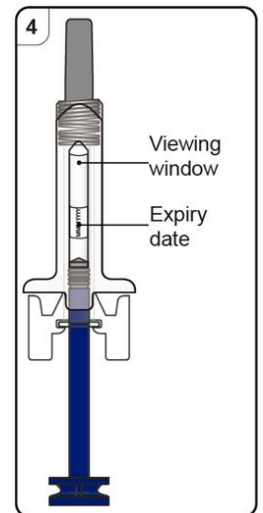
**Do not** attempt to remove the air.

- **Do not** use the pre-filled syringe if liquid is cloudy or contains visible particles.

- **Do not** use the pre-filled syringe if it appears to be damaged or if it has leaked.

- **Do not** use the pre-filled syringe after the expiry date (EXP), which is printed on the pre-filled syringe label and carton.

In all of these cases, contact your doctor, nurse or pharmacist.

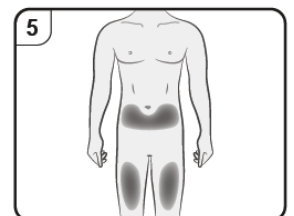


#### Step 5: Choose injection site

You should inject into the front of the thighs or the lower stomach area **but not** the area 5 cm around the belly button.

**Do not** inject into skin that is tender, bruised, red, scaly, hard or into areas with scars or stretch marks.

If your caregiver, doctor or nurse is giving you the injection, they may also inject into the upper arm.



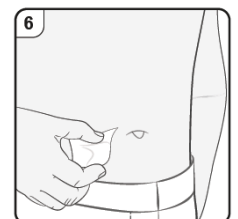
### Inject with JUBBONTI

#### Step 6: Clean injection site

Wash your hands with soap and water.

Clean the chosen injection site with an alcohol wipe. Leave it to dry before injecting.

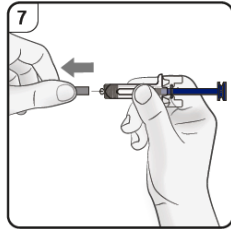
**Do not** touch or blow on the cleaned area before injecting.



### Step 7: Remove needle cap

Firmly pull straight to remove the needle cap from the pre-filled syringe. You may see a drop of liquid at the end of the needle. This is normal.

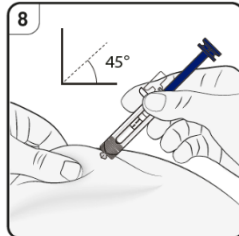
**Do not** put the needle cap back on. Throw away the needle cap.



### Step 8: Insert needle

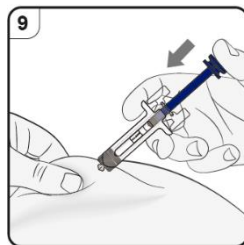
Gently pinch the skin at the injection site and hold the pinch throughout the injection. With the other hand insert the needle into the skin at an angle of approximately 45 degrees as shown.

**Do not** press the plunger while inserting the needle.



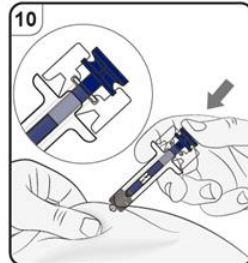
### Step 9: Start injection

Continue to pinch the skin. Slowly press the plunger **as far as it will go**. This will ensure that a full dose is injected.



### Step 10: Complete injection

Confirm that the plunger head is between the safety guard wings as shown. This will ensure that the safety guard has been activated and will cover the needle after the injection is finished.



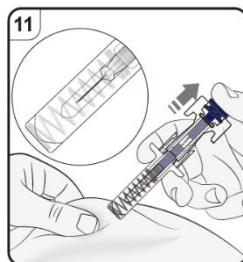
### Step 11: Release plunger

Keeping the pre-filled syringe at the injection site, slowly release the plunger until the needle is covered by the safety guard.

Remove the pre-filled syringe from the injection site and release the pinch.

There may be a small amount of blood at the injection site. You can press a cotton ball or gauze pad over the injection site until any bleeding stops.

**Do not** rub the injection site. If needed, cover the injection site with a small adhesive plaster.



### After the injection

#### Step 12: Dispose of the pre-filled syringe

Put the pre-filled syringe in a sharps disposal container immediately after use. **Do not** throw away the pre-filled syringe into household waste.

Talk to your doctor or pharmacist about proper disposal of the sharps disposal container. There may be local regulations for disposal.



#### If you miss a dose of JUBBONTI

If you miss a dose, JUBBONTI should be administered as soon as possible. From then on, JUBBONTI should be scheduled every 6 months from the date of the last injection.

#### If you are given too much JUBBONTI

If you think that you or anyone else has received too much JUBBONTI, you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

## 5. What should I know while using JUBBONTI?

### Things you should do

- take calcium and vitamin D supplements if your doctor has told you to. Most people do not get enough calcium and vitamin D in their diet and supplements are needed to help strengthen bones.
- practice good dental hygiene while being treated with JUBBONTI. Your routine dental hygiene should include brushing your teeth and tongue after every meal, including the evening and gentle flossing once a day to remove plaque. Use a mirror and check your teeth and gums regularly for any changes such as sores or bleeding gums. If you notice any problems, tell your doctor and dentist immediately.
- tell any doctor, dentist, nurse, or pharmacist you visit that you are using JUBBONTI.
- if you are about to be started on any other medicine,
- remind your doctor, nurse or pharmacist that you are being treated with JUBBONTI.
- attend all your doctor's appointments so that your progress can be checked. Your doctor may recommend you to have some tests, X-rays and/or bone density scans from time to time to make sure the medicine is working.

### Call your doctor straight away if you:

- have spasms, twitches, aches or cramps in your muscles, and/or numbness or tingling in your fingers, toes or around your mouth, or have seizures. You may have low levels of calcium in your blood.
- experience any problems with your mouth or teeth such as loose teeth or ill-fitting dentures, pain, or swelling while being treated with JUBBONTI.
- develop a swollen, red area of skin, most commonly in the lower leg, that feels hot and tender (cellulitis) and sometimes experienced with fever and chills.
- experience new or unusual pain in your hip, groin, or thigh. Some people have developed unusual fractures in their thigh bone while being treated with JUBBONTI. These fractures may occur with little or no trauma and may involve both thigh bones. This side effect is very rare.
- experience shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin. If you experience any of these side effects you may be having an allergic reaction to JUBBONTI. These side effects are rare.
- have a severe allergic reaction with skin rash, blisters or fever
- notice any purple or brownish-red spots, hives or skin sores. This may be an allergic reaction that can damage blood vessels mainly in the skin. This side effect is very rare.
- become pregnant while using JUBBONTI. Your doctor can discuss with you the risks of having it while you are pregnant. Females that are menstruating should ensure they have adequate contraception while taking JUBBONTI.

### Things you should not do

- Do not stop using JUBBONTI without talking to your doctor. After your treatment with JUBBONTI is stopped, or if you skip or delay taking a dose, your risk of breaking bones in your spine is increased, especially if you have a history of broken bones in the spine. If your JUBBONTI treatment is stopped, discuss other available treatment options with your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how JUBBONTI affects you.**

JUBBONTI has no known effects on the ability to drive or use machines but, as a general precaution, if you are driving soon after an injection, arrange to have someone else drive.

### Looking after your medicine

If you need to store your JUBBONTI before use, follow the instructions in the carton on how to take care of your medicine properly.

- Store JUBBONTI in the refrigerator between 2 and 8°C. Do not freeze.

- Keep your medicine in the original carton to protect from light. If you remove the medicine from the carton it may not keep well.
- Your medicine may be left outside the refrigerator to reach room temperature (up to 25°C) before injection. This will make the injection more comfortable.
- Once your medicine has been left to reach room temperature (up to 25°C), it must be used within 30 days. Throw away the pre-filled syringe that has been stored at room temperature after 30 days.
- Do not keep JUBBONTI at temperatures above 25°C. Warm temperatures will affect how JUBBONTI works.
- Do not shake the pre-filled syringe.

**Keep it where young children cannot reach it.**

### When to discard your medicine

JUBBONTI is for single-use in one patient only. Dispose of any unused or expired medicine as instructed below.

### Getting rid of any unwanted medicine

Your doctor or nurse is likely to dispose of JUBBONTI for you. However, if you need to get rid of this medicine because you no longer need to use it or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Muscle and skeleton:</b></p> <ul style="list-style-type: none"><li>• back, muscle or joint pain, or stiffness, most commonly affecting the hips, knees and spine</li><li>• pain in the arms or legs</li><li>• aching muscle, muscle tenderness or weakness, not caused by exercise</li></ul> <p><b>Skin and hair:</b></p> <ul style="list-style-type: none"><li>• unusual hair loss or thinning</li><li>• itchy, red or dry skin</li></ul> <p><b>Ears:</b></p> <ul style="list-style-type: none"><li>• ear pain, discharge from the ear and/or an ear infection. These could be signs of bone damage in the ear</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Eyes:</b> <ul style="list-style-type: none"> <li>blurred or cloudy vision</li> </ul>	
<b>General:</b> <ul style="list-style-type: none"> <li>high cholesterol levels in the blood</li> </ul>	

## Serious side effects

Serious side effects	What to do
<b>Signs of an allergic reaction:</b> <ul style="list-style-type: none"> <li>shortness of breath</li> <li>wheezing or difficulty breathing.</li> <li>swelling of the face, lips, tongue or other parts of the body</li> <li>rash, itching or hives on the skin.</li> <li>rash that may occur on the skin or sores in the mouth</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>
<b>Signs of low blood calcium (hypocalcaemia):</b> <ul style="list-style-type: none"> <li>muscle spasms, twitches, aches or cramps</li> <li>numbness or tingling in your fingers, toes or around your mouth</li> <li>seizures</li> </ul>	
<b>Signs of problems with your mouth, teeth or jaw:</b> <ul style="list-style-type: none"> <li>persistent pain or swelling and/or non-healing sores in your mouth or jaw</li> <li>loose teeth</li> </ul>	
<b>Signs of bone fractures:</b> <ul style="list-style-type: none"> <li>bone, joint and/or muscle pain, including pain in your hip, groin, or thigh, which is sometimes severe</li> <li>pain in spine</li> </ul>	
<b>Signs of skin infection:</b> <ul style="list-style-type: none"> <li>develop a swollen, red area of skin that feels hot and tender (cellulitis) and sometimes experienced with fever and chills</li> <li>skin rash or blisters with fever</li> </ul>	
<b>Gut and digestion:</b> <ul style="list-style-type: none"> <li>pain in upper abdomen (belly) that may be accompanied by back pain, nausea, vomiting, fever and/or sweating</li> </ul>	
<b>Brain and nerves:</b> <ul style="list-style-type: none"> <li>pain in the extremities, such as hands and feet</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What JUBBONTI contains

<b>Active ingredient (main ingredient)</b>	denosumab
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>glacial acetic acid</li> <li>sorbitol</li> <li>polysorbate 20</li> <li>hydrochloric acid</li> <li>sodium hydroxide</li> <li>water for injections</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What JUBBONTI looks like

JUBBONTI is a clear, colourless to slightly yellowish or slightly brownish solution supplied in a pre-filled syringe with safety guard.

JUBBONTI comes in a single pack size containing 60 mg of denosumab in a volume of 1.0 mL (60 mg/1.0 mL) (Aust R 418515).

Each pack contains one ready to use single-use pre-filled syringe and one calendar card with a sticker.

The needle cover on the pre-filled syringe is not made with natural rubber latex.

### Who distributes JUBBONTI

Sandoz Pty Ltd  
100 Pacific Highway  
North Sydney, NSW 2060  
Australia  
Tel 1800 726 369

This leaflet was prepared in August 2024.

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