Product name:		Territory:
Conexxence (Deno) 60mg PFS		**UK**
Type of packaging:	Dosage:	
Leaflet IFU	**1**	
Material number:	2-D-Matrix-Code:	
M0FO0014/00 UK	**M0FO0014/00 UK**	
Pharma-Code (Laetus):	EAN-Code:	
-	-	
Dimension:	Font:	Size:
588 x 360 mm	**Interstate**	**10**
Folded format: 155 x 65 mm		

Colours:	Indication only – not to be printed:
• Black	• Fold lines
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• Magenta	
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Peter Schaffer	

1. Draft	**19.08.2025, 15.15**	
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Package leaflet: Information for the patient

Conexxence 60 mg solution for injection in pre-filled syringe

denosumab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects

Read all of this leaflet carefully before you start using 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 only. 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. This includes any possible side effects not listed in this leaflet. See section 4.
- Your doctor will give you a patient reminder card, which contains important safety information you need to be aware of before and during your treatment with Conexxence.

What is in this leaflet

1. What Conexxence is and what it is used for

What Conexxence is and how it works
Conexxence contains denosumab, a protein (monoclonal antibody) that interferes with the action of another protein, in order to treat bone loss and osteoporosis. Treatment with Conexxence makes bone stronger and less likely to break.

Bone is a living tissue and is renewed all the time. Oestrogen helps keep bones healthy. After the menopause, oestrogen level drops which may cause bones to become thin and fragile. This can eventually lead to a condition called osteoporosis. Osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone. It can also occur in patients receiving glucocorticoids. Many patients with osteoporosis have no symptoms, but they are still at risk of breaking bones, especially in the spine, hips and wrists.

Surgery or medicines that stop the production of oestrogen or testosterone used to treat patients with breast or prostate cancer can also lead to bone loss. The bones become weaker and break more easily.

What Conexxence is used for
Conexxence is used to treat:
- osteoporosis in women after the menopause (postmenopausal) and men who have an increased risk of fracture (broken bones), reducing the risk of spinal, non-spinal and hip fractures.
- bone loss that results from a reduction in hormone (testosterone) level caused by surgery or treatment with medicines in patients with prostate cancer.
- bone loss that results from long-term treatment with glucocorticoids in patients who have an increased risk of fracture.

2. What you need to know before you use Conexxence

Do not use Conexxence
- if you have low calcium levels in the blood (hypocalcaemia).
- if you are allergic to denosumab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using Conexxence.

Whilst being treated with Conexxence you may develop a skin infection with symptoms such as a swollen, red area of skin, most commonly in the lower leg, that feels hot and tender (cellulitis), and possibly with symptoms of fever. Please tell your doctor immediately if you develop any of these symptoms.

You should also take calcium and vitamin D supplements while being on treatment with Conexxence. Your doctor will discuss this with you.

You may have low levels of calcium in your blood while receiving Conexxence. Please tell your doctor immediately if you notice any of the following symptoms: spasms, twitches, or cramps in your muscle, and/or numbness or tingling in your fingers, toes or around your mouth, and/or seizures (fits), confusion, or loss of consciousness.

Tell your doctor if you have or have ever had severe kidney problems, kidney failure or have needed dialysis or are taking medicines called glucocorticoids (such as prednisolone or dexamethasone), which may increase your risk of getting low blood calcium if you do not take calcium supplements.

Problems with your mouth, teeth or jaw
A side effect called osteonecrosis of the jaw (ONJ) (bone damage in the jaw) has been reported rarely (may affect up to 1 in 1 000 people) in patients receiving Conexxence for osteoporosis. The risk of ONJ increases in patients treated for a long time (may affect up to 1 in 200 people if treated for 10 years). ONJ can also occur after stopping treatment. It is important to try to prevent ONJ developing as it may be a painful condition that can be difficult to treat. In order to reduce the risk of developing ONJ, take the following precautions:

Before receiving treatment, tell your doctor or nurse (health care professional) if you:
- have any problems with your mouth or teeth such as poor dental health, gum disease, or a planned tooth extraction.
- don't receive routine dental care or have not had a dental check-up for a long time.
- are a smoker (as this may increase the risk of dental problems).
- have previously been treated with a bisphosphonate (used to treat or prevent bone disorders).
- are taking medicines called corticosteroids (such as prednisolone or dexamethasone).
- have cancer.

Your doctor may ask you to undergo a dental examination before you start treatment with Conexxence.

While being treated, you should maintain good oral hygiene and receive routine dental check-ups. If you wear dentures you should make sure these fit properly. If you are under dental treatment or will undergo dental surgery (e.g. tooth extractions), inform your doctor about your dental treatment and tell your dentist that you are being treated with Conexxence.

Contact your doctor and dentist immediately if you experience any problems with your mouth or teeth such as loose teeth, pain or swelling, or non-healing of sores or discharge, as these could be signs of ONJ.

Unusual thigh bone fractures
Some people have developed unusual fractures in their thigh bone while being treated with Conexxence. Contact your doctor if you experience new or unusual pain in your hip, groin, or thigh.

Children and adolescents
Conexxence should not be used in children and adolescents under 18 years of age.

Other medicines and Conexxence
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important that you tell your doctor if you are being treated with another medicine containing denosumab.

You should not use Conexxence together with another medicine containing denosumab.

Pregnancy and breast-feeding
Conexxence has not been tested in pregnant women. It is important to tell your doctor if you are pregnant, think you may be pregnant; or plan to get pregnant. Conexxence is not recommended for use if you are pregnant. Women of child-bearing potential should use effective methods of contraception while being treated with Conexxence and for at least 5 months after stopping treatment with Conexxence.

If you become pregnant during treatment with Conexxence or less than 5 months after stopping treatment with Conexxence, please inform your doctor.

It is not known whether Conexxence is excreted in breast milk. It is important to tell 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 using Conexxence, considering the benefit of breast-feeding to the baby and the benefit of Conexxence to the mother.

If you are breast-feeding during Conexxence treatment, please inform your doctor.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines
Conexxence has no or negligible influence on the ability to drive and use machines.

Conexxence contains sorbitol
This medicine contains 47 mg sorbitol in each ml of solution.

Conexxence contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per 60 mg, that is to say essentially 'sodium-free'.

Conexxence contains polysorbate 20
This medicine contains 0.1 mg of polysorbate 20 in each pre-filled syringe which is equivalent to 0.1 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Conexxence

The recommended dose is one pre-filled syringe of 60 mg administered once every 6 months, as a single injection under the skin (subcutaneous). The best places to inject are the top of your thighs and the abdomen. Your carer can also use the outer area of your upper arm. Please consult your doctor on the date for a potential next injection.

You should also take calcium and vitamin D supplements while being on treatment with Conexxence. Your doctor will discuss this with you.

Your doctor may decide that it is best for you or a carer to inject Conexxence. Your doctor or healthcare provider will show you or your carer how to use Conexxence. For instructions on how to inject Conexxence, please read the section at the end of this leaflet.

Do not shake.

If you forget to use Conexxence
If a dose of Conexxence is missed, the injection should be administered as soon as possible. Thereafter, injections should be scheduled every 6 months from the date of the last injection.

If you stop using Conexxence
To get the most benefit from your treatment in reducing the risk of fractures, it is important to use Conexxence for as long as your doctor prescribes it for you. Do not stop your treatment without contacting your doctor.

4. Possible side effects

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

Uncommonly, patients receiving Conexxence may develop skin infections (predominantly cellulitis). **Please tell your doctor immediately** if you develop any of these symptoms while being on treatment with Conexxence: swollen, red area of skin, most commonly in the lower leg, that feels hot and tender, and possibly with symptoms of fever.

Rarely, patients receiving Conexxence may develop pain in the mouth and/or jaw, swelling or non-healing of sores in the mouth or jaw, discharge, numbness or a feeling of heaviness in the jaw, or loosening of a tooth. These could be signs of bone damage in the jaw (osteonecrosis). **Tell your doctor and dentist immediately** if you experience such symptoms while being treated with Conexxence or after stopping treatment.

Rarely, patients receiving Conexxence may have low calcium levels in the blood (hypocalcaemia). Symptoms include spasms, twitches, or cramps in your muscles, and/or numbness or tingling in your fingers, toes or around your mouth and/or seizures, confusion, or loss of consciousness. If any of these apply to you, **tell your doctor immediately**. Low calcium in the blood may also lead to a change in heart rhythm called QT prolongation which is seen by electrocardiogram (ECG).

Rarely unusual fractures of the thigh bone may occur in patients receiving Conexxence. **Contact your doctor** if you experience new or unusual pain in your hip, groin or thigh as this may be an early indication of a possible fracture of the thigh bone.

Rarely, allergic reactions may occur in patients receiving Conexxence. Symptoms include swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin, wheezing or difficulty breathing. **Please tell your doctor** if you develop any of these symptoms while being treated with Conexxence.

Very common side effects (may affect more than 1 in 10 people):
- bone, joint, and/or muscle pain which is sometimes severe,
- arm or leg pain (pain in extremity).

Common side effects (may affect up to 1 in 10 people):
- painful urination, frequent urination, blood in the urine, inability to hold your urine,
- upper respiratory tract infection,
- pain, tingling or numbness that moves down your leg (sciatica),
- constipation,
- abdominal discomfort,
- rash,
- skin condition with itching, redness and/or dryness (eczema),
- hair loss (alopecia).

Uncommon side effects (may affect up to 1 in 100 people):
- fever, vomiting and abdominal pain or discomfort (diverticulitis),
- ear infection,
- rash that may occur on the skin or sores in the mouth (lichenoid drug eruptions).

Very rare side effects (may affect up to 1 in 10 000 people):
- allergic reaction that can damage blood vessels mainly in the skin (e.g. purple or brownish-red spots, hives or skin sores) (hypersensitivity vasculitis).

Not known (frequency cannot be estimated from the available data):
- 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.

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

5. How to store Conexxence

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 label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C - 8 °C).
Do not freeze.
Keep the container in the outer carton in order to protect from light.

Your pre-filled syringe 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 syringe has been left to reach room temperature (up to 25 °C), it must be used within 30 days.

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 will help to protect the environment.

6. Contents of the pack and other information

What Conexxence contains
- The active substance is denosumab. Each 1 ml pre-filled syringe contains 60 mg of denosumab (60 mg/ml).
- The other ingredients are acetic acid, sodium acetate trihydrate, sorbitol (E420), polysorbate 20 (E432), and water for injections.

What Conexxence looks like and contents of the pack
Conexxence is a clear, colourless to slightly yellow solution for injection provided in a ready to use pre-filled syringe. Each pack contains one pre-filled syringe with a needle guard.

Marketing Authorisation Holder
Fresenius Kabi Limited
Cestrian Court
Eastgate Way, Manor Park
Runcorn, Cheshire, WA7 1NT
United Kingdom

Manufacturer
Fresenius Kabi Austria GmbH
Hafnerstrasse 36
8055 Graz
Austria

This leaflet was last revised in May 2025.

Conexxence®
60 mg/mL
Solution for injection in pre-filled syringe
denosumab
Subcutaneous use.
Fresenius Kabi
M0FO0014/00 UK

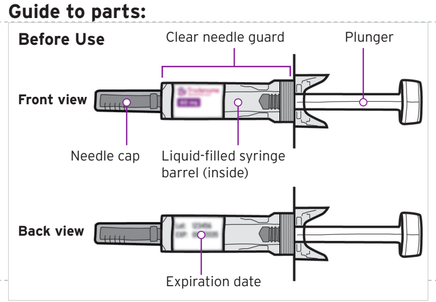
Conexxence®
60 mg/mL
Solution for injection in pre-filled syringe
denosumab
Subcutaneous use.
Fresenius Kabi

7. Instructions for use

Conexxence®

60 mg/ml
Solution for injection in pre-filled syringe
denosumab
Subcutaneous use.

Guide to parts:



Before you use a Conexxence pre-filled syringe with automatic needle guard, read this important information:

- It is important that you do not try to give yourself the injection unless you have received training from your doctor or healthcare provider.
- Conexxence is given as an injection into the tissue just under the skin (subcutaneous injection).
- **Do not** remove the grey needle cap from the pre-filled syringe until you are ready to inject.
- **Do not** use the pre-filled syringe if the carton is damaged or the seal is broken.
- **Do not** use the pre-filled syringe if it has been dropped on a hard surface. Use a new pre-filled syringe and call your doctor or healthcare provider.
- **Do not** try to push the plunger rod of the pre-filled syringe before the injection.
- **Do not** shake the pre-filled syringe.
- **Important:** Keep the pre-filled syringe out of the sight and reach of children.

Storing Conexxence pre-filled syringe

- Store Conexxence in a refrigerator between 2 °C to 8 °C in the original carton. **Do not** freeze.
- Before giving the injection, Conexxence may be allowed to reach room temperature up to 25 °C in the original container. This takes 15 to 30 minutes. **Do not** warm Conexxence in any other way.
- After Conexxence is removed from the refrigerator, it must be used within **30 days**. If not used in 30 days, it should be thrown away (discarded).
- **Do not** use Conexxence after the expiration date printed on the label.
- Protect Conexxence from direct light and heat.

Call your doctor or healthcare provider if you have any questions.

Step 1 Prepare materials

1.1 Gather supplies

On a clean, well-lit work surface, gather the supplies needed for your injection (see **Figure A**):

- alcohol wipes
- cotton ball or gauze pad
- adhesive bandage
- sharps disposal container (see **Step 4 Throw away your pre-filled syringe**)

Figure A

1.2 Wait 15 to 30 minutes for the pre-filled syringe to reach room temperature

Remove the carton from the refrigerator (see **Figure B**) and place it on a flat surface.

Let it warm at room temperature for 15 to 30 minutes (see **Figure C**)

Do not try to warm the pre-filled syringe by using a heat source such as hot water or microwave.

Do not leave the pre-filled syringe in direct sunlight.

Do not shake the pre-filled syringe

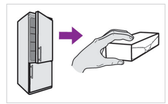


Figure B

Figure C

Keep the pre-filled syringe out of sight and reach of children.

1.3 Wash your hands

Wash your hands well with soap and water and dry them with a clean towel (see **Figure D**).

Figure D

1.4 Remove pre-filled syringe from tray

Place two fingers on either side, in the middle of the clear needle guard. Pull the pre-filled syringe straight up and out of the tray (see **Figure E**).

Do not grasp the plunger.

Do not grasp the needle cap.

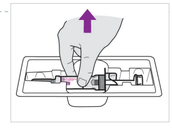


Figure E

1.5 Inspect pre-filled syringe and medicine

Check the pre-filled syringe to make sure that:

- The name on the label says Conexxence (see **Figure F**).
- The expiration date on the label has not passed.
- The pre-filled syringe is not cracked or broken.

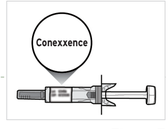


Figure F

Check the liquid to see if there are any particles or discoloration (see **Figure G**).

Do not use the pre-filled syringe if:

- The name on the label is not Conexxence.
- The expiration date on the label has passed.
- Any part appears cracked or broken.
- The needle cap is missing or not firmly attached.
- The medicine is cloudy or there are particles in it. It must be a clear, colourless to slightly yellow solution.

In all cases, use a new pre-filled syringe and call your doctor or healthcare provider.

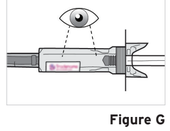


Figure G

Step 2 Prepare to inject

2.1 Choose an injection site

You can inject into (see **Figure H**):

- upper thighs
- belly, except for a 5 cm area around the belly button
- outer area of upper arm (if you are injecting into someone else)

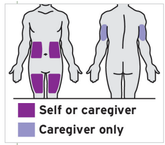


Figure H

Do not inject into areas where the skin is tender, bruised, red, or hard.

Avoid injecting into areas with scars or stretch marks

2.2 Clean the injection site

Clean the injection site with an alcohol wipe (see **Figure I**).

Let your skin air dry.

Do not blow on or touch the injection site after cleaning.

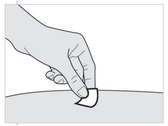


Figure I

2.3 Remove needle cap

Carefully pull the needle cap straight off and away from your body (see **Figure J**). It may take some force to remove the needle cap.

Do not remove the needle cap from the pre-filled syringe until you are ready to inject.

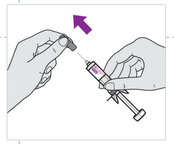


Figure J

Do not hold the pre-filled syringe by the plunger rod.

Do not twist or bend the needle cap.

Throw away (dispose of) the needle cap in your sharps disposal container (see **Step 4 Throw away your pre-filled syringe**).

Do not put the needle cap back onto the pre-filled syringe.

Do not touch the needle or let it touch any surface after removal of the needle cap.

Step 3 Inject medicine

3.1 Pinch the skin

Pinch your injection site to create a firm surface (see **Figure K**).

Note: It is important to keep the skin pinched when injecting.

Figure K

3.2 Insert the needle

Quickly insert the needle straight into the pinched skin at a 45 to 90-degree angle (see **Figure L**).

Do not inject into muscle or blood vessel.

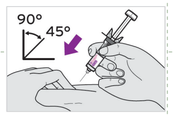


Figure L

3.3 Inject

Push the plunger with slow and constant pressure (see **Figure M**) until you cannot press anymore and have injected all of the liquid under the skin (subcutaneously) (see **Figure N**). You may hear or feel a "click".

Do not lift the pre-filled syringe off the skin.

Figure M

Figure N

3.4 Release plunger

Slowly release the plunger and allow the needle to come out of the skin at the same angle it was inserted. The clear needle guard will safely cover the needle (see **Figure O**).

Do not put the needle cap back on the needle.

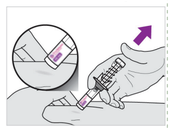


Figure O

3.5 Treat injection site

If there is blood or liquid at the injection site, gently press a cotton ball or gauze on the skin (see **Figure P**).

You may use an adhesive bandage if needed.

Do not rub the injection site.

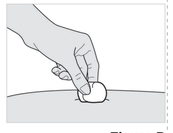


Figure P

Step 4 Throw away your pre-filled syringe

4.1 Dispose

Put your used pre-filled syringe and needle cap in a sharps disposal container right away after use (see **Figure Q**).

Medicines should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Figure Q

Do not reuse the pre-filled syringe.

Do not throw away (dispose of) used syringes in your household trash.

Do not recycle your used sharps disposal container.

Keep Conexxence pre-filled syringes, sharps disposal container and all medicines out of the reach and sight of children.

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