

## Consumer Medicine Information

**Please read this leaflet carefully before you start using Arixtra. You may wish to keep it to read again.**

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### What is in this leaflet

This leaflet answers some common questions about Arixtra.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you using Arixtra against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

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### What Arixtra is used for

Arixtra is used to prevent blood clots forming in patients who are recovering from orthopaedic or abdominal surgery. Arixtra is also used to treat blood clots once they have formed. Arixtra contains the medication fondaparinux sodium, a synthetic compound which helps prevent blood clots forming in blood vessels. This type of blood clot, also called deep venous thrombosis, or DVT, can occur in patients who are confined to bed after hip or knee surgery.

Your doctor may have prescribed Arixtra for another reason. Ask your doctor if you have any questions about why Arixtra has been prescribed for you.

Arixtra is not addictive.

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

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### Before you are given Arixtra

*When you must not be given it*

**You should not be given Arixtra if you have any of the following conditions:**

- You are bleeding excessively
- You have severe kidney disease
- You have acute bacterial endocarditis (an infection of the heart)

**Do not use Arixtra if you have an allergy to it or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction to Arixtra may include skin rash, itchiness, shortness of breath, or difficulty breathing.

**Do not use Arixtra if you are pregnant or intend to become pregnant.**

Arixtra is not recommended for use during pregnancy, unless you and your doctor or pharmacist have discussed the risks and benefits involved.

**Do not use Arixtra if you are breast-feeding or plan to breast-feed.**

It is not known whether Arixtra passes into human breast milk.

**Do not use Arixtra after the expiry date (EXP) printed on the pack.**

If you use this medicine after the expiry date has passed, it may not work as well as it should.

**Do not use Arixtra if the packaging is torn or shows signs of tampering.**

**If you are not sure whether you should start using Arixtra, talk to your doctor or pharmacist.**

*Before you are given it*

**Tell your doctor or pharmacist if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes
- latex

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

Your doctor or pharmacist will discuss the possible risks and benefits of using Arixtra during pregnancy.

**Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.**

Your doctor or pharmacist will discuss the possible risks and benefits of using Arixtra during breast-feeding.

**Tell your doctor or pharmacist if you have or have had any medical conditions, especially the following:**

- a stomach ulcer
- bleeding disorders
- recent bleeding inside the head
- recent surgery on the brain, eye, or spinal column
- moderate or severe kidney disease or severe liver disease
- heparin induced thrombocytopenia (low platelet count).

Tell your doctor or pharmacist if you are elderly or have a low body weight (less than 50 kg) as you may be at increased risk of bleeding if you are given Arixtra.

It is recommended that your doctor monitor your blood platelets at the beginning and end of your treatment with Arixtra.

**If you have not told your doctor or pharmacist about any of the above, tell them before you start using Arixtra.**

*Taking other medicines*

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

Some medicines and Arixtra may interfere with each other.

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while using Arixtra.

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### How Arixtra is given

*How much is given*

The usual dose of Arixtra is 2.5 mg given once a day, starting after your operation. Arixtra may be given for up to 31 days.

*How it is given*

Arixtra is given to you as a subcutaneous injection (an injection just under the skin). Arixtra should not be given as an intramuscular injection (an injection into the muscle). The injections can be given by a doctor or nurse, or you may be taught how to give the injections to yourself.

Instructions on how to use the Arixtra syringe are contained in the package insert in each Arixtra carton.

*Overdose*

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

If you think that you or anyone else may have been given too much Arixtra, immediately telephone your doctor or contact the Poisons Information Centre (telephone 13 11 26) for advice on overdose management or go to accident and emergency at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning.

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### While you are using Arixtra

*Things you must do*

**Tell any other doctors, dentists, and pharmacists who are treating you that you are using Arixtra.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are using Arixtra.**

**Immediately tell your doctor if you develop the following:**

- pain or swelling in the legs
- chest pain or difficulty in breathing

These may be signs that a blood clot has formed.

If you have epidural or spinal anaesthesia (a pain killing injection around the spinal cord), tell your doctor or nurse immediately if you have back pain, numbness or weakness in the legs, or problems with bowel or bladder function.

*Things you must not do*

**Do not give Arixtra to anyone else, even if they have the same condition as you.**

**Do not use Arixtra to treat any other complaints unless your doctor or pharmacist tells you to.**

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### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Arixtra.**

Arixtra helps most people at risk of blood clots following surgery, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Ask your doctor or pharmacist to answer any questions you may have.**

**If you get any side effects, do not stop using Arixtra without first talking to your doctor or pharmacist.**

**Tell your doctor or pharmacist if you notice any of the following:**

- bleeding
- oozing of fluid from the wound
- unusual tiredness, weakness or drowsiness
- fever
- nausea or vomiting
- indigestion or gastritis
- low blood pressure
- fainting or vertigo
- dizziness or confusion
- difficulty sleeping
- pain or skin reactions at the injection site
- itching sensation on the skin
- urinary tract infection
- difficulty or pain when passing urine
- diarrhoea or constipation
- swelling (oedema)
- shortness of breath
- flushing of the skin

These side effects of Arixtra are usually mild.

**Tell your doctor or pharmacist immediately if you notice any of the following:**

- allergic reaction. Symptoms of an allergic reaction may include:
  - shortness of breath, wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin
- significant bleeding

These may be signs of serious side effects. You may need urgent medical attention. Serious side effects are rare.

**The following side effects may be identified by tests performed by your doctor:**

- blood disorders such as decreased or abnormal blood platelets, clotting disorders or excess bilirubin
- changes in liver function or liver enzymes

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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## After using Arixtra

### *Storage*

Arixtra will normally be stored in the pharmacy or on the hospital ward. The injection should be kept at room temperature (less than 25°C).

### *Disposal*

**If your doctor or pharmacist tells you to stop using Arixtra or the injections have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

### *What it looks like*

Arixtra comes as a pre-filled safety syringe, in pack sizes of 2 pre-filled syringes.

### *Ingredients*

Active ingredients:

- fondaparinux sodium

Other ingredients:

- sodium chloride
- water for injections

### *Manufacturer*

Arixtra is supplied in Australia by:

**Aspen Pharmacare Australia Pty Ltd**  
 34-36 Chandos Street  
 St Leonards NSW 2065  
 Australia

Arixtra has the following Registration No:  
 2.5 mg - AUST R 80279

This leaflet was prepared on 30 July 2014.