

Pregabalin-AFT

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 Pregabalin-AFT?

Pregabalin-AFT contains the active ingredient pregabalin. Pregabalin-AFT is used to treat neuropathic pain and to control epilepsy. It also has pain relieving effects.

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

2. What should I know before I use Pregabalin-AFT?

Do not use if you have ever had an allergic reaction to pregabalin or any of the ingredients listed at the end of the CMI.

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.

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

3. What if I am taking other medicines?

Some medicines may interfere with Pregabalin-AFT 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 do I take Pregabalin-AFT?

- Follow the instructions provided to you by your doctor carefully.
- Your doctor will tell you the dose which you need to take each day.

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

5. What should I know while using Pragabalin-AFT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Pregabalin-AFT.• Tell your doctor if, for any reason, you have not taken Pregabalin-AFT exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily
Things you should not do	<ul style="list-style-type: none">• Do not stop taking Pregabalin-AFT, or lower the dosage, without checking with your doctor.• Do not take Pregabalin-AFT to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Pregabalin-AFT may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, symptoms such as dizziness and drowsiness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25 °C. do not refrigerate.• Use within 90 days of opening.

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

6. Are there any side effects?

Like all medicines, Daptomycin-AFT can cause 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.

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.

Pregabalin-AFT

Active ingredient: *Pregabalin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Pregabalin-AFT. **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 Pregabalin-AFT.**

Where to find information in this leaflet:

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

1. Why am I using Pregabalin-AFT?

Pregabalin-AFT contains the active ingredient pregabalin.

Pregabalin-AFT belongs to a group of medicines called anticonvulsants. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

Pregabalin-AFT is used to treat neuropathic pain, which is pain caused by an abnormality of, or damage to, the nerves.

Pregabalin-AFT is also used to control epilepsy. Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

Pregabalin-AFT also has pain relieving effects. Pregabalin-AFT may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may prescribe Pregabalin-AFT in addition to your current therapy when your current treatment is no longer working as well as before.

Ask your doctor if you have any questions about why Pregabalin-AFT has been prescribed for you.

Your doctor may have prescribed it for another reason. This medicine is available only with a doctor's prescription.

2. What should I know before I use Pregabalin-AFT?

Warnings

Do not use Pregabalin-AFT if:

- you are allergic to pregabalin, or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.

Some of the 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

Do not use this medicine if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have allergies to:
 - any other medicines, especially barbiturates or any other anticonvulsant medicines
 - any other substances, such as foods, preservatives or dyes
- have or have had any of the following medical conditions:
 - congestive heart failure
 - hereditary problems with galactose metabolism
 - kidney problems
 - diabetes
 - depression

Tell your doctor if you have a history of substance abuse.

There have been reported cases of misuse and abuse with pregabalin.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Pregabalin-AFT is not recommended for use during pregnancy.

Pregabalin use during the first 3 months of pregnancy may cause birth defects in the unborn child that require medical treatment. Abnormalities of the face (orofacial clefts), the eyes, the nervous system (including the brain), kidneys and genitals have been reported.

Effective contraception must be used by women of childbearing potential.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in Pregabalin-AFT passes into breast milk and its safety in infants is unknown. It is recommended that you do not breastfeed while taking Pregabalin-AFT.

Use in children

There is not enough information to recommend the use of this medicine in children under the age of 18 years.

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.

Some medicines may be affected by Pregabalin-AFT or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Pregabalin-AFT and certain other medicines may influence each other.

When taken with certain other medicines which reduce the activity of the brain, Pregabalin-AFT may increase the side effects seen with these medicines, and could lead to respiratory failure, coma and death. The degree of dizziness, sleepiness and decreased concentration may be increased if Pregabalin-AFT is taken together with medicines containing oxycodone (a pain-killer), lorazepam (used for treating anxiety), and alcohol.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat allergies (antihistamines).
- medicines used to treat certain psychiatric disorders.

Taking these medicines together with Pregabalin-AFT may increase your chance of experiencing side effects. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Pregabalin-AFT.

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

4. How do I take Pregabalin-AFT?

- Follow the instructions provided to you by your doctor carefully. They may differ from the information contained in this leaflet.
- If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much to take

- Your doctor will tell you the dose which you need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.
- Your doctor may recommend that you start with a low dose of Pregabalin-AFT and slowly increase the dose to the lowest amount needed to control your epilepsy/convulsions or neuropathic pain.

- The usual dose range is 150 mg per day to 600 mg per day given in two divided doses.

When to take Pregabalin-AFT

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How to take Pregabalin-AFT

Pregabalin-AFT is for oral use only.

1. Open the bottle: Press downward on the cap and turn it counterclockwise (Figure 1).
2. First time use only: A Press-In Bottle Adapter (PIBA) is provided with the oral syringe. This is the device that gets inserted into the neck of the bottle to make it easier to withdraw the solution using the oral syringe. If the PIBA is not already in place, remove the PIBA and 5 ml oral syringe from the plastic overwrap. With the bottle on a flat surface, insert the PIBA into the bottle neck while keeping the PIBA's flat surface facing up and pressing on it (Figure 2).
3. Push the syringe plunger to the bottom of the barrel of the syringe (toward its tip) to remove excess air. Attach the syringe to the PIBA with a slight twisting motion (Figure 3).
4. Invert the bottle (with the syringe attached) and fill the syringe with the liquid by pulling the syringe plunger down to just beyond the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 4). Remove air bubbles from the syringe by pushing the plunger up to the appropriate graduation mark.
5. Return the bottle to an upright position with the syringe still in the PIBA/bottle (Figure 5).
6. Remove the syringe from the bottle/PIBA (Figure 6).
7. Empty the contents of the syringe directly into mouth by pushing the syringe plunger to the bottom of the syringe barrel (Figure 7).

Note: Steps 4-7 may need to be repeated up to three times to obtain the total dose (Table 1). [For example, a 150 mg (7.5 ml) dose will require two withdrawals from the bottle to achieve the entire dose. Using the oral syringe, first withdraw 5 ml and empty contents of syringe directly into the mouth, then refill the oral syringe with 2.5 ml and empty the remaining contents into the mouth.]
8. Rinse the syringe by drawing water into the syringe and pushing the syringe plunger to the bottom of the syringe barrel, at least three times (Figure 8).
9. Replace the cap on the bottle (leaving the PIBA in place in the bottle neck) (Figure 9).

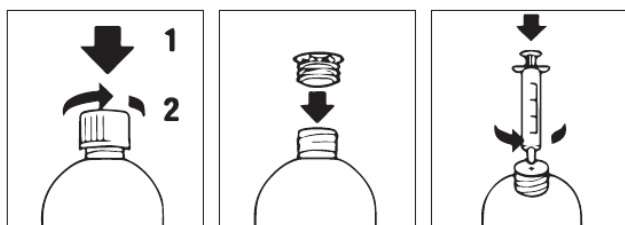


Figure 1

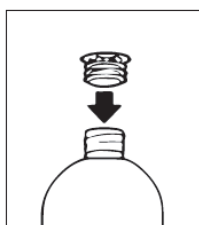


Figure 2

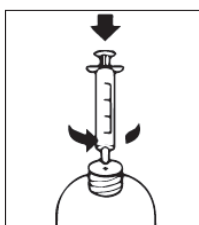


Figure 3

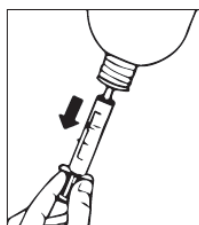


Figure 4

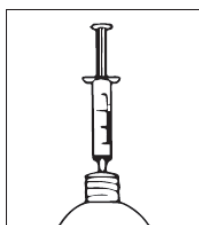


Figure 5

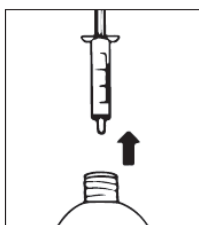


Figure 6

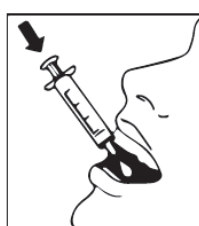


Figure 7

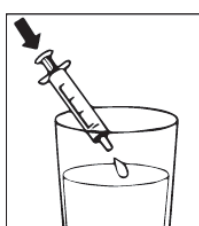


Figure 8

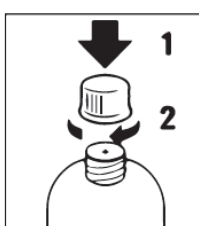


Figure 9

Table 1: Oral syringe withdrawals to deliver prescribed dose of Pregabalin-AFT

Pregabalin dose (mg)	Total solution volume (ml)	First syringe withdrawal (ml)	Second syringe withdrawal (ml)	Third syringe withdrawal (ml)
25	1.25	1.25	Not required	Not required
50	2.5	2.5	Not required	Not required
75	3.75	3.75	Not required	Not required
100	5	5	Not required	Not required
150	7.5	5	2.5	Not required
200	10	5	5	Not required
225	11.25	5	5	1.25
300	15	5	5	5

How long to take Pregabalin-AFT

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine, even if you feel well.

Do not stop taking Pregabalin-AFT, or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping Pregabalin-AFT suddenly may worsen your condition or cause unwanted effects such as sleeplessness, headache, nausea (feeling sick), anxiety, excessive sweating or diarrhoea (runny stools). If appropriate, your doctor will slowly reduce your dose before you can stop taking it completely.

If you forget to use Pregabalin-AFT

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much Pregabalin-AFT

If you think that you have used too much Pregabalin-AFT, you may need urgent medical attention.

You should immediately:

- phone the Australian Poisons Information Centre (**by calling 13 11 26**), or the New Zealand National Poisons Information Centre (**telephone 0800 POISON or 0800 764 766**), 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.

You may need urgent medical attention.

Symptoms of an overdose with Pregabalin-AFT may include mood changes, feeling tired, confusion, depression, agitation, restlessness or seizures.

5. What should I know while using Pregabalin-AFT?

Things you should do

Call your doctor straight away if you:

- experience any changes in your vision. Pregabalin-AFT may cause blurring or other changes in eyesight. Your doctor may ask you to stop taking Pregabalin-AFT to improve these symptoms.
- have any thoughts of suicide or self-harm, any unusual changes in mood or behaviour, or show signs of depression. Some people taking medicines to treat convulsions, such as Pregabalin-AFT, have had thoughts of harming themselves or taking their life. Patients and caregivers should be alert and monitor for these effects. Signs and symptoms of suicidal risk include:
 - thoughts or talk of death or suicide.
 - thoughts or talk of self-harm or harm to others.
 - any recent attempts of self-harm.
 - new or an increase in aggressive behaviour, irritability or agitation.
 - new or worsening depression.

Mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs of suicide while taking Pregabalin-AFT, contact your doctor or a mental health professional right away.

Tell your doctor if you feel Pregabalin-AFT is not helping your condition. Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken Pregabalin-AFT exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking Pregabalin-AFT.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

Things you should not do

- Do not take Pregabalin-AFT to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Pregabalin-AFT affects you.

As with other anticonvulsant medicines, Pregabalin-AFT may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, symptoms such as dizziness and drowsiness may be worse.

Looking after your medicine

- Store below 25 °C.
- Do not refrigerate.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

Use within 90 days of opening.

Getting rid of any unwanted medicine

If you no longer need to use this medicine 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?

Pregabalin-AFT helps most people with neuropathic pain or epilepsy, but it may have unwanted side effects in a few people. 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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pregabalin-AFT.

It can be difficult to tell whether side effects are the result of taking Pregabalin-AFT, effects of your condition or side effects of other medicines you may be taking. For this reason, it is important to tell your doctor of any change in your condition.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the list of side effects. You may not experience any of them.

If you get any side effects, do not stop taking Pregabalin-AFT without first talking to your doctor or pharmacist.

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

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
Digestion/gastro-intestinal-related: <ul style="list-style-type: none">• Constipation• Diarrhea• Nausea Alertness-related: <ul style="list-style-type: none">• Feeling tired or drowsy• Dizziness• Unsteadiness when walking, reduced co-ordination, shaking or tremors Body as a whole: <ul style="list-style-type: none">• Headache• Increase in weight• Dry mouth• Blurred or double vision	Speak to your doctor if you have any of these less serious side effects and they worry you. These are common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
<p>Mood/behaviour-related:</p> <ul style="list-style-type: none">unusual changes in mood or behavioursigns of new or increased irritability or agitationsigns of depression <p>Pain/swelling/enlargement-related:</p> <ul style="list-style-type: none">swelling of the hands, ankles or feetenlargement of breastsunexplained muscle pain, tenderness and weakness <p>Urine-related:</p> <ul style="list-style-type: none">passing little to no urine	<p>Tell your doctor as soon as possible if you notice any of these serious side effects.</p> <p>These are serious side effects that may require medical attention. Serious side effects are rare.</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">shortness of breath, swelling of the feet and legs, weight increase due to fluid build-upirritated red eyes that are sensitive to lightmore frequent or more severe seizures (fits)sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing.	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>You may need urgent medical attention or hospitalisation. These side effects are very rare.</p>

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

Other side effects not listed above may also occur in some people. Some of these side effects (for example, changes in blood pressure) can only be found when your doctor does tests from time to time to check your progress.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to:

- Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems (for Australia) or
- <https://nzphvc.otago.ac.nz/reporting/> (for New Zealand).

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 Pregabalin-AFT contains

Active ingredient (main ingredient)	Pregabalin
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">Monobasic sodium phosphate monohydrateDibasic sodium phosphateSucraloseMethyl hydroxybenzoateFlavouring agent: Strawberry flavourPurified water

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

What Pregabalin-AFT looks like

Pregabalin-AFT 20 mg/mL oral solution is a clear colourless solution in a bottle containing 473 mL of oral solution, in a cardboard carton. The carton also contains, in a clear polyethylene wrap, a graduated 5 mL oral syringe and a press-in bottle adaptor (PIBA). (Aust R 325431).

Who distributes Pregabalin-AFT

AFT Pharmaceuticals Pty Ltd.
PO Box 748
North Ryde, Sydney, NSW 1670
Australia

AFT Pharmaceuticals Ltd.
Auckland

Email: customer.service@aftpharm.com

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