AMITRIPTYLINE VIATRIS

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking AMITRIPTYLINE VIATRIS?

AMITRIPTYLINE VIATRIS contains the active ingredient amitriptyline hydrochloride. AMITRIPTYLINE VIATRIS is used to treat depression. It can also be used to treat bedwetting, provided that there is no physical cause for the problem (e.g. problems with the bladder).

For more information, see Section 1. Why am I taking AMITRIPTYLINE VIATRIS? in the full CMI.

2. What should I know before I take AMITRIPTYLINE VIATRIS?

Do not take if you have ever had an allergic reaction to AMITRIPTYLINE VIATRIS 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 take AMITRIPTYLINE VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AMITRIPTYLINE VIATRIS 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 AMITRIPTYLINE VIATRIS?

- For depression, the usual starting dose is 75 mg to 150 mg per day in divided doses.
- The doses recommended for bedwetting are lower than the doses used to treat depression and usually depend on the person's age and weight.
- More instructions can be found in Section 4. How do I take AMITRIPTYLINE VIATRIS? in the full CMI.

5. What should I know while taking AMITRIPTYLINE VIATRIS?

Things you should do	• Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes. • Keep all of your appointments with your doctor so that your progress can be checked. • Remind any doctor, dentist or pharmacist you visit that you are taking AMITRIPTYLINE VIATRIS.
Things you should not do	• Do not stop taking AMITRIPTYLINE VIATRIS, or lower the dose, without checking with your doctor. • Do not take AMITRIPTYLINE VIATRIS to treat any other conditions unless your doctor tells you to.
Driving or using machines	• AMITRIPTYLINE VIATRIS may reduce your alertness, or cause drowsiness or dizziness in some people. If affected, do not drive, operate machinery or do anything else that could be dangerous. • Children should not ride a bike or do anything else that can be dangerous if they are drowsy.
Drinking alcohol	• Combining AMITRIPTYLINE VIATRIS with alcohol can make you more drowsy or dizzy. • Your doctor may suggest you avoid alcohol while being treated for depression.
Looking after your medicine	• Keep AMITRIPTYLINE VIATRIS where children cannot reach it. • Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while taking AMITRIPTYLINE VIATRIS? in the full CMI.

6. Are there any side effects?

Tell your doctor if you notice any of the following and they worry you: dry mouth, altered sense of taste, nausea (feeling sick), vomiting, diarrhoea, constipation, blurred vision, difficulty in focusing, drowsiness, tiredness, headache, dizziness, lightheadedness, increased sweating, weight gain or loss or changes in sex drive.

Tell your doctor immediately or go to the Emergency department at the nearest hospital if you notice any of the following: skin rash, itching, hives; swelling of the face or tongue; fever, swollen lymph nodes, severe sunburn, blistering or swelling of the skin, fainting or collapse, chest pain and seizures or fits.

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.

AMITRIPTYLINE VIATRIS

Active ingredient: *amitriptyline hydrochloride*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I taking AMITRIPTYLINE VIATRIS?
2. What should I know before I take AMITRIPTYLINE VIATRIS?
3. What if I am taking other medicines?
4. How do I take AMITRIPTYLINE VIATRIS?
5. What should I know while taking AMITRIPTYLINE VIATRIS?
6. Are there any side effects?
7. Product details

1. Why am I taking AMITRIPTYLINE VIATRIS?

AMITRIPTYLINE VIATRIS contains the active ingredient amitriptyline hydrochloride.

AMITRIPTYLINE VIATRIS is used to treat depression.

AMITRIPTYLINE VIATRIS 10 mg and AMITRIPTYLINE VIATRIS 25 mg tablets can be taken at any stage in the treatment of depression. However, the highest strength, AMITRIPTYLINE VIATRIS 50 mg, is approved only for the maintenance treatment of depression (after your symptoms have improved).

AMITRIPTYLINE VIATRIS belongs to a group of medicines called tricyclic antidepressants (TCAs). TCA medicines work by correcting the imbalance of certain chemicals in the brain. These chemicals, called amines, are involved in controlling mood. By correcting this imbalance, TCAs can help relieve the symptoms of depression.

AMITRIPTYLINE VIATRIS can also be used to treat bedwetting, provided that there is no physical cause for the problem (e.g. problems with the bladder).

Ask your doctor if you have any questions about why AMITRIPTYLINE VIATRIS has been prescribed for you.

Your doctor may have prescribed AMITRIPTYLINE VIATRIS for another reason.

AMITRIPTYLINE VIATRIS is not approved for use in children and adolescents below 18 years of age for the treatment of depression.

The safe use and effectiveness of AMITRIPTYLINE VIATRIS in treating the above condition, for this age group, has not been established.

2. What should I know before I take AMITRIPTYLINE VIATRIS?

Warnings

Do not take AMITRIPTYLINE VIATRIS if:

- **you are allergic to amitriptyline, or any of the ingredients listed at the end of this leaflet.**
  Some of the symptoms of an allergic reaction may include:
  - skin rash, itching or hives
  - swelling of the face, lips, tongue or other parts of the body
  - shortness of breath, wheezing or difficulty breathing
- Always check the ingredients to make sure you can take this medicine.
- **Do not take AMITRIPTYLINE VIATRIS if you have recently had a heart attack.**
  Taking AMITRIPTYLINE VIATRIS could make your condition worse.
- **Do not take AMITRIPTYLINE VIATRIS if you are taking cisapride, a medicine used to treat stomach reflux.**
  Combining AMITRIPTYLINE VIATRIS with cisapride may cause serious side effects such as an abnormal heart rhythm.
- **Do not take AMITRIPTYLINE VIATRIS if the packaging shows signs of tampering or the tablets do not look quite right.**

Do not take AMITRIPTYLINE VIATRIS if you are taking, or have taken within the last 14 days, another medicine for depression called a monoamine oxidase inhibitor (MAOI).

Taking AMITRIPTYLINE VIATRIS with a MAOI or taking it too soon after stopping a MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will tell you when it is safe to start taking AMITRIPTYLINE VIATRIS after stopping the MAOI.

Ask your doctor or pharmacist if you are unsure if you are taking or have been taking a MAOI.

MAOIs are medicines used to treat depression and symptoms of Parkinson's disease. Examples of MAOIs are phenelzine, tranylcypromine, moclobemide and selegiline.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- **Have, or have had any other medical conditions, especially the following:**
  - heart or blood vessel problems

- liver problems
- glaucoma, a condition where there is an increased pressure in the eye
- urinary problems such as difficulty in passing urine
- thyroid problems
- seizures or fits
- any mental illness other than depression, for example schizophrenia or manic depression (alternating periods of elation/overactivity and depressed mood)
- family history of suicide or mania

- **Tell your doctor if you plan to undergo any type of surgery or if you are undergoing electroshock therapy.**
- Tell your doctor if you take any medicines for any other condition.
- Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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.

There have been reports of some babies experiencing complications immediately after delivery. Your doctor will discuss the possible risks and benefits of taking AMITRIPTYLINE VIATRIS during pregnancy.

Do not take AMITRIPTYLINE VIATRIS if you are breastfeeding.

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

AMITRIPTYLINE VIATRIS passes into breast milk and may harm your baby.

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.

Do not take AMITRIPTYLINE VIATRIS if you are taking:

- cisapride, a medicine used to treat stomach reflux
- any monoamine oxidase inhibitor (MAOI) such as:
  - phenelzine, tranylcypromine or moclobemide which are used to treat depression
  - selegiline, used to treat symptoms of Parkinson's disease.

  Wait at least 14 days after stopping your MAOI before starting AMITRIPTYLINE VIATRIS.

Tell your doctor if you are taking or have recently taken any other medicines, such as valproic acid.

Some medicines may be affected by AMITRIPTYLINE VIATRIS or may affect how well AMITRIPTYLINE VIATRIS works. These include:

- selective serotonin reuptake inhibitors (SSRIs), a group of medicines used to treat depression and other mental illnesses, such as fluoxetine, sertraline and paroxetine. This could result in "serotonin syndrome". This condition may include feeling agitated or restless, confused, loss of muscle coordination or twitching muscles and shivering
- some medicines used to treat high blood pressure
- anticholinergics, found in some medicines used to relieve stomach cramps; travel sickness; hayfever and allergies; cough and colds. This could result in high fever, particularly during hot weather. If you take these medicines together, you may feel drowsier and experience dry mouth, constipation and dizziness for a longer period of time. Also, you may be more at risk of developing seizures and neuroleptic malignant syndrome. Neuroleptic malignant syndrome may include sudden increase in body temperature, sweating, fast heartbeat, muscle stiffness, high blood pressure and convulsions
- medicines used to treat mental disorders such as schizophrenia
- quinidine and flecainide, medicines used to control an irregular heartbeat
- cimetidine, a medicine used to treat reflux and ulcers
- sleeping tablets/sedatives, anti-anxiety medicines
- medicines for epilepsy
- thyroid medicines
- disulfiram, a medicine used to deter alcohol consumption
- tramadol, a medicine used to relieve pain.

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

4. How do I take AMITRIPTYLINE VIATRIS?

How much to take

- The dose varies from person to person.
- Your doctor will decide the right dose for you.
- Follow the instructions provided and take AMITRIPTYLINE VIATRIS until your doctor tells you to stop.

Depression

AMITRIPTYLINE VIATRIS is usually started at a low dose and then, if necessary, increased depending on how your symptoms improve and how well you tolerate it.

For depression, the usual starting dose is 75 mg to 150 mg per day in divided doses.

For people being treated in hospital for their depression, the usual starting dose is 100 mg to 200 mg per day.

For the elderly, lower doses are recommended as AMITRIPTYLINE VIATRIS may not be well tolerated in this age group.

Your doctor may then reduce your dose to 50 mg to 100 mg per day when your depressive symptoms have improved, depending on your response to AMITRIPTYLINE VIATRIS.

Bed-wetting

Keep AMITRIPTYLINE VIATRIS out of the reach of children.

Do not give your child more AMITRIPTYLINE VIATRIS than what is recommended by your doctor.

The doses recommended for bedwetting are lower than the doses used to treat depression and usually depend on the person's age and weight.

When to take AMITRIPTYLINE VIATRIS

- AMITRIPTYLINE VIATRIS can be taken with or without food.
- AMITRIPTYLINE VIATRIS can be taken as a single dose (e.g. at bedtime) or as divided doses (e.g. three times a day). Your doctor will advise you.
- **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.

How to take AMITRIPTYLINE VIATRIS

- Swallow the tablets whole with a glass of water.

How long to take AMITRIPTYLINE VIATRIS for

- **Depression**
  - **Keep taking AMITRIPTYLINE VIATRIS for as long as your doctor recommends.**
    The length of treatment will depend on how quickly your symptoms improve.
  - Most medicines for depression take time to work, so do not be discouraged if you do not feel better right away. Some people notice an improvement in their depressive symptoms after 3 or 4 days. However, it may take up to 4 weeks to feel the full benefits of AMITRIPTYLINE VIATRIS.
  - Even when you feel well, your doctor may ask you to continue taking AMITRIPTYLINE VIATRIS for 3 months or longer to make sure that the benefits last.
- **Bed-wetting**
  - Most children respond to treatment in the first few days. However, continued treatment is usually required to maintain the response until bed-wetting ends.

If you forget to take AMITRIPTYLINE VIATRIS

- **If you take one dose a day (at bedtime):**
  - **If you forget to take AMITRIPTYLINE VIATRIS before going to bed and wake up late in the night or early in the morning, do not take the missed dose until you have checked with your doctor.**
    You may have difficulty waking up or experience drowsiness in the morning or during the day if you take AMITRIPTYLINE VIATRIS at these times.
- **If you take more than one dose a day:**
  - **If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**
  - **Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**
  - **Do not take a double dose to make up for the dose you missed.**

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

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

If you take too much AMITRIPTYLINE VIATRIS

Taking too much AMITRIPTYLINE VIATRIS at once can be dangerous and may cause death.

If you think that you have taken too much AMITRIPTYLINE VIATRIS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

If you take too much AMITRIPTYLINE VIATRIS, you may feel drowsy, cold, very dizzy or have a fast or irregular heartbeat.

You may also have fits, difficulty breathing or lose consciousness.

Keep AMITRIPTYLINE VIATRIS out of the reach of children.

Children are much more sensitive than adults to medicines such as AMITRIPTYLINE VIATRIS. An accidental overdose is especially dangerous in children.

5. What should I know while taking AMITRIPTYLINE VIATRIS?

Things you must do

Tell your doctor immediately if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. These symptoms may continue or get worse during the first one to two months of treatment until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in children, adolescents and young adults under 25 years of age.

Contact your doctor or a mental health professional right away or go to the nearest hospital for treatment if you or someone you know is showing any of the following warning signs of suicide:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Tell your doctor straight away if you develop a rash, fever, facial swelling or enlarged lymph nodes.

Tell your doctor if you feel the tablets are not helping your condition.

Keep all of your appointments with your doctor so that your progress can be checked.

Tell your doctor immediately if you become pregnant while taking AMITRIPTYLINE VIATRIS. Do not stop taking your tablets until you have spoken to your doctor.

Before starting any new medicine, tell your doctor or pharmacist that you are taking AMITRIPTYLINE VIATRIS.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking AMITRIPTYLINE VIATRIS.

If you plan to have surgery, including dental surgery, tell your doctor or dentist that you are taking AMITRIPTYLINE VIATRIS.

Your doctor may ask you to temporarily stop taking AMITRIPTYLINE VIATRIS a few days before elective surgery.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Things you must not do

- **AMITRIPTYLINE VIATRIS may reduce your alertness,** cause drowsiness or dizziness in some people. If affected, do not drive, operate machinery or do anything else that could be dangerous. Children should not ride a bike, climb trees or do anything else that could be dangerous if they are drowsy.
- **Do not stop taking AMITRIPTYLINE VIATRIS, or lower the dose, without checking with your doctor.**
- **Do not let yourself run out of your medicine over weekends or during holidays**.
- Stopping AMITRIPTYLINE VIATRIS suddenly may make you feel sick (nauseous), have headaches or feel generally unwell. Your doctor will tell you how to gradually reduce the amount of AMITRIPTYLINE VIATRIS you are taking before stopping completely.
- **Do not take AMITRIPTYLINE VIATRIS to treat any other conditions unless your doctor tells you to.**
- **Do not give AMITRIPTYLINE VIATRIS to anyone else, even if they have the same condition as you.**

Be careful getting up from a sitting or lying position

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Tell your doctor or dentist if your mouth continues to feel dry for more than 2 weeks.

AMITRIPTYLINE VIATRIS may cause dry mouth. This can be relieved by frequent sips of water, sucking sugarless lollies or chewing sugarless gum. However, continuing dryness of the mouth may increase the chance of dental disease, including tooth decay and gum disease.

Driving or using machines

Do not drive or operate machinery until you know how AMITRIPTYLINE VIATRIS affects you.

AMITRIPTYLINE VIATRIS may reduce your alertness, cause drowsiness or dizziness in some people. If you experience any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful drinking alcohol while taking AMITRIPTYLINE VIATRIS.

Combining AMITRIPTYLINE VIATRIS with alcohol can make you more drowsy or dizzy. Your doctor may suggest you avoid alcohol while being treated for depression.

Looking after your medicine

- **Keep your tablets where the temperature stays below 25°C.**

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.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take 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
• dry mouth, altered sense of taste • nausea (feeling sick), vomiting • diarrhoea, constipation • blurred vision, difficulty in focusing • drowsiness, tiredness, headache • dizziness, lightheadedness • increased sweating • weight gain or loss • changes in sex drive.	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• fast or irregular heartbeats • larger breast than normal (in men and women) • tingling or numbness of the hands or feet • uncontrolled movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs • difficulty in passing urine • signs of frequent infections such as fever, chills, sore throat or mouth ulcers • yellowing of the eyes or skin (jaundice) • unusual bruising or bleeding • feeling anxious, restless or confused • abnormal ideas, hallucinations • sudden switch of mood to one of excitement, overactivity • talkativeness and uninhibited behaviour.	**Tell your doctor as soon as possible if you notice any of these side effects which are serious and may require medical attention.**

Very serious side effects

Very serious side effects	What to do
• skin rash, itching, hives; swelling of the face or tongue; severe sunburn, blistering or swelling of the skin, fever, swollen lymph nodes • fainting or collapse • chest pain • seizures or fits.	**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.** **You may require urgent medical attention or even hospitalisation.**

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. 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 AMITRIPTYLINE VIATRIS contains

Active ingredient (main ingredient)	10 mg, 25 mg or 50 mg of amitriptyline hydrochloride
Other ingredients (inactive ingredients)	• lactose monohydrate • microcrystalline cellulose • disodium edetate • sodium starch glycollate • pregelatinised maize starch • colloidal anhydrous silica • magnesium stearate • purified talc [10 mg and 50 mg only] • Opadry Blue OY-B-30904 (ID 3525) [10 mg only] • Opadry Yellow OY-LS-32814 (ID 2734) [25 mg only] • Opadry Buff OY-LS-37200 (ID 3249) [50 mg only].
Potential allergens	Soya bean product [10 mg only], sugars as lactose and traces of sulfites.

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

What AMITRIPTYLINE VIATRIS looks like

AMITRIPTYLINE VIATRIS 10 mg is a 7 mm, normal convex, blue film coated tablet debossed with 'AP10' on one side and α on the other (AUST R 232796).

AMITRIPTYLINE VIATRIS 25 mg is a 7 mm yellow, film coated, normal convex tablet marked AP/25 on one side, α on reverse (AUST R 232797)

AMITRIPTYLINE VIATRIS 50 mg is a 8 mm hexagonal, tan film coated tablet marked AP 50 on one side, α on reverse (AUST R 232798).

Who distributes AMITRIPTYLINE VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: 1800 274 276

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