

APO-Desvenlafaxine MR Tablets

Contains the active ingredient desvenlafaxine (as benzoate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about APO-Desvenlafaxine MR Tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Desvenlafaxine MR Tablets. It contains the active ingredient desvenlafaxine (as benzoate).

It is used in the treatment and prevention of relapse of depression. Depression can affect your whole body and may cause emotional and physical symptoms such as feeling low in spirit, being unable to enjoy life, poor appetite or overeating, disturbed sleep, loss of sex drive, lack of energy and feeling guilty over nothing.

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

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

How it works

This medicine contains the active ingredient called desvenlafaxine benzoate. It belongs to a class of medications called Serotonin-Noradrenaline Reuptake Inhibitors (SNRIs).

Serotonin and noradrenaline are chemical messengers that allow certain nerves in the brain to work.

This medicine increases the level of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

There is no evidence that this medicine is addictive.

It is available only with a doctor's prescription.

Use in children

This medicine should not be used in children or adolescents under 18 years of age.

The safety and effectiveness of this medicine in this age group have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are taking other medications for depression known as monoamine oxidase inhibitors, even if you have stopped taking them, but have taken them within the last 14 days.**

- **You are allergic to, desvenlafaxine, venlafaxine or any of the ingredients listed at the end of this leaflet.**

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

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor

immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - a history of fits (seizures or convulsions)
 - a personal history or family history of bipolar disorder
 - blood pressure problems
 - glaucoma (increased pressure in the eye)
 - a tendency to bleed more than normal or you are taking a blood thinning medication
 - raised cholesterol or lipid levels
 - problems with your kidneys or liver
 - problems with your heart
 - low sodium levels in your blood
 - or any other medical conditions.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

One of these risks is that newborn babies whose mothers have been taking this medicine may have several problems including breathing difficulties, seizures and lack of oxygen in their blood.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your

doctor have discussed the risks and benefits involved.

This medicine passes into breast milk and there is a possibility that the breastfed baby may be affected.

5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines.

This includes vitamins and supplements or natural therapies you buy without a prescription that are available from your pharmacy, supermarket, naturopath or health food shop, such as St John's wort or tryptophan supplements.

Taking other medicines

Some medicines may interact with desvenlafaxine. These include:

- Medications for depression known as monoamine oxidase inhibitors (MAOIs) (such as moclobemide, phenelzine and tranylcypromine).

Tell your doctor if you are taking or have stopped taking them within the last 14 days.

Ask your doctor or pharmacist if you are unsure if you are taking any of these medicines.

It is important that you do not take this medicine or medicines similar to desvenlafaxine with MAOIs or within 14 days of taking an MAOI as this may result in a serious life-threatening condition.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines:

- any other medications for bipolar disorder, depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder, including St John's wort.
- drugs that affect serotonin levels e.g. tramadol, dextromethorphan, fentanyl, methadone and pentazocine.

- medicines for weight loss
- triptans (used to treat migraine)
- linezolid (used to treat infections)
- drugs that affect your tendency to bleed, e.g., aspirin, NSAIDs, warfarin.

If you are taking any of these you may need a different dose or you may need to take different medicines.

- Your doctor will advise you.

Other medicines not listed above may also interact with desvenlafaxine.

Switching to this medicine from other antidepressants

Side effects from discontinuing antidepressant medication may occur if you are switched from other antidepressants, including venlafaxine, to this medicine. Your doctor may gradually reduce the dose of your initial antidepressant medication to help reduce these side effects.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose is 50 mg taken once daily with or without food.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

If you have kidney problems you may need a lower dose of desvenlafaxine.

How to take it

Swallow the tablets whole with a glass of water or other non-alcoholic liquid.

Do not divide, crush, chew or place the tablets in water.

Do not be concerned if you see a tablet 'shell' in your faeces after taking this medicine.

As the tablet travels the length of your gastrointestinal tract, the active ingredient desvenlafaxine is slowly released. The tablet 'shell' remains undissolved and is eliminated in your faeces. Therefore, even though, you may see a tablet 'shell' in your faeces, your dose of desvenlafaxine has been absorbed.

When to take it

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

It does not matter if you take it before, with or after food.

How long to take it for

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

Although you may begin to feel better after two weeks, it may take several weeks before you feel much better. It is important to give this medicine time to work.

This medicine helps to control your condition, so it is important to keep taking your medicine even if you feel well.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is less than 12 hours until your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep the telephone number for these places handy whilst taking any medications.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up so that your progress can be checked.

Always discuss any questions you have about this medicine with your doctor.

Take this medicine as your doctor has prescribed.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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.

Watch carefully for signs that your depression is getting worse, especially in the first few weeks of treatment or if your dose has changed.

Sometimes people with depression can experience a worsening of their depressive symptoms. This can happen even when taking an antidepressant.

Tell your doctor there is the potential for a false positive urinary drug screen while on this medicine.

Tell your doctor immediately if you experience any of the following symptoms, especially if they are severe, you have not had these symptoms before or they happen very suddenly.

- anxiety or agitation
- panic attacks
- difficulty sleeping
- irritability
- aggressiveness
- hostility or impulsiveness
- restlessness
- overactivity or uninhibited behaviour
- other unusual changes in behaviour
- thoughts of suicide.

Tell your doctor immediately if you have any thoughts about suicide or doing harm to yourself.

Warning signs of suicide:

If you or someone you know is showing the following warning signs, contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment.

All thoughts or talk about suicide or violence are serious.

- Thoughts or talk about death or suicide

- Thoughts or talk about self-harm or doing harm to others
- Any recent attempts of self-harm
- An increase in aggressive behaviour, irritability or agitation.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor. Your doctor may want to slowly decrease your dose of this medicine to help avoid side effects. Side effects are known to occur when people stop taking this medicine, especially when they suddenly stop therapy. Some of these side effects include:
 - headache
 - nausea
 - dizziness
 - tiredness
 - irritability
 - anxiety
 - abnormal dreams
 - diarrhoea
 - excessive sweating.
 Slowly reducing the amount of this medicine being taken reduces the possibility of these effects occurring.

Things to be careful of

Avoid drinking alcohol while you are taking this medicine.

Be careful when driving or operating machinery until you know how this medicine affects you. It may make you feel drowsy.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are

taking desvenlafaxine or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- Stomach, bowel or urinary tract problems:
 - nausea or vomiting
 - loss of appetite
 - diarrhoea
 - constipation
 - difficulty passing urine.
- Changes in your behaviour:
 - difficulty sleeping, abnormal sleepiness or abnormal dreams
 - sexual function problems such as decreased sex drive, delayed ejaculation, problems achieving erection or difficulties achieving orgasm
 - nervousness or anxiety
 - feeling jittery or irritable.
- Difficulty thinking or working because of:
 - yawning
 - disturbances in concentration
 - fainting or dizziness after standing up
 - fatigue
 - rapid heart beat
 - chills
 - headache.
- Changes in your appearance:
 - excessive sweating
 - hot flushes
 - rash
 - weight loss or weight gain
- Blurred vision
- Ringing in the ears
- Altered taste, dry mouth.

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects and you may need medical attention:

- Muscle spasms, stiffness, weakness or movement disorders
- Abnormal facial movements such as tongue thrusting, repetitive

chewing, jaw swinging, or grimacing

- A feeling of apathy or not caring about things
- Feeling detached from yourself
- Hallucinations, confusion
- Agitation
- Unusually overactive
- Problems with breathing, shortness of breath
- Bleeding or bruising more easily than normal
- Numbness or pins and needles
- Sensitivity to sunlight.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- swelling of the face, lips, tongue, throat or other parts of the body
- seizures or fits
- symptoms of sudden fever with sweating, rapid heartbeat and muscle stiffness, which may lead to loss of consciousness.

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

Some of these side effects (for example, increase in blood pressure, increase in blood cholesterol, changes to liver function, protein in the urine) can only be found when your doctor does tests from time to time to check your progress.

This is not a complete list of all possible side effects. There may be some side effects not yet known.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to desvenlafaxine, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Desvenlafaxine MR Tablet looks like

50 mg Tablet

Light pink, biconvex, round shaped, film coated tablets debossed

with "DV" on one side and "50" on the other side.

Blister pack of 7, 14 and 28 tablets.

100 mg Tablet

Reddish-orange, biconvex, round shaped, film coated tablets, debossed with "DV" on one side and "100" on the other side.

Blister pack of 7, 14 and 28 tablets.

* Not all strengths and/or pack sizes may be available.

Ingredients

Each modified release tablet contains 50 mg or 100 mg of desvenlafaxine benzoate as the active ingredient.

It also contains the following inactive ingredients:

- Cellulose-microcrystalline,
- purified talc,
- stearic acid,
- colloidal anhydrous silica,
- magnesium stearate,
- hypromellose.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Desvenlafaxine MR 50 mg Tablet (Blister Pack): AUSTR No. - 218307

APO-Desvenlafaxine MR 100 mg Tablet (Blister Pack): AUSTR No. - 227802

Sponsor

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