

Desvenlafaxine GH XR

Desvenlafaxine as benzoate extended release tablets 50 mg and 100 mg

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Desvenlafaxine GH XR.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist or asking questions.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Desvenlafaxine GH XR against the expected benefits it will have for you.

If you have any questions about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT DESVENLAFAXINE GH XR TABLETS ARE USED FOR

What it does

Desvenlafaxine GH XR 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 it for another reason.

How it works

Desvenlafaxine GH XR 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. Desvenlafaxine GH XR tablets increase the level of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

Desvenlafaxine GH XR is not addictive. It is available only with a doctor's prescription.

BEFORE YOU TAKE DESVENLAFAXINE GH XR

When you must not take it

Do not take Desvenlafaxine GH XR 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.

Do not take Desvenlafaxine GH XR if you are allergic to

desvenlafaxine, venlafaxine or to any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction 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.

Do not give Desvenlafaxine GH XR to children or adolescents under 18 years of age.

The safety and effectiveness of Desvenlafaxine GH XR in this age group have not been established.

Do not take this medicine after the expiry date (EXP) printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

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

Desvenlafaxine GH XR is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of taking Desvenlafaxine GH XR if you are pregnant.

One of these risks is that newborn babies whose mothers have been taking Desvenlafaxine GH XR may have several problems including breathing difficulties, seizures and lack of oxygen in their blood.

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

Desvenlafaxine GH XR passes into breast milk and there is a possibility that the breastfed baby may be affected. For this reason, the use of

Desvenlafaxine GH XR is not recommended in breast-feeding women.

Tell your doctor if 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
- Any other medical conditions.

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start to take Desvenlafaxine GH XR.

Taking other medicines

Tell your doctor or pharmacist if you take

any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop, such as St John's Wort or tryptophan supplements.

Do not start to take any other medicine while you are taking Desvenlafaxine GH XR, unless it is prescribed or approved by your doctor.

Some medicines may interfere with Desvenlafaxine GH XR or Desvenlafaxine GH XR may interfere with these medicines. 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 Desvenlafaxine GH XR or medicines similar to Desvenlafaxine GH XR 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, including sibutramine
- Triptans (used to treat migraine)
- Linezolid (used to treat infections)
- Drugs that affect your tendency to bleed eg: Aspirin, NSAIDS, Warfarin.

You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Desvenlafaxine GH XR.

Switching to Desvenlafaxine GH XR from other antidepressants

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

HOW TO TAKE DESVENLAFAXINE GH XR

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it
Swallow the tablets whole with a glass of water or other nonalcoholic 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 Desvenlafaxine GH XR.

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.

How much to take
The usual dose is 50 mg taken once daily with or without food.

Do not change your dose unless your doctor tells you to.

Your doctor will gradually increase your dose if needed. If you have kidney problems, you may need a lower dose of Desvenlafaxine GH XR.

When to take it
Desvenlafaxine GH XR should be taken once daily and can be taken with or without food.

Take Desvenlafaxine GH XR at approximately the same time each day.

This could be either in the morning or in the evening.

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

How long to take it
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 Desvenlafaxine GH XR time to work.

This medicine helps to control your condition,

so it is important to keep taking your medicine even if you feel well.

If you forget to take it
If it is less than 12 hours until your next dose, skip the dose you missed and then take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking as you would normally.

Do not take a double dose to make up for the dose 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 when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)
Immediately telephone your doctor or the Poisons Information Centre (tel: 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have

**taken too much
Desvenlafaxine GH XR.**

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
DESVENLAFAXINE GH
XR**

Things you must do
Visit your doctor regularly for a check up so that your progress can be checked. Always discuss any questions you have about Desvenlafaxine GH XR with your doctor.

Take Desvenlafaxine GH XR tablets as your doctor has prescribed.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Keep enough Desvenlafaxine GH XR tablets to last weekends and holidays.

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 Desvenlafaxine GH XR.

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 behavior.
- 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 to be careful of
Be careful driving or operating dangerous machinery until you know how Desvenlafaxine GH XR affects you.

Desvenlafaxine GH XR tablets may make you feel drowsy.

Things you must not do

Do not stop taking Desvenlafaxine GH XR or change the dose without the advice of your doctor, even if you feel better.

Your doctor may want to slowly decrease your dose of Desvenlafaxine GH XR to help avoid side effects. Side effects are known to occur when people stop taking Desvenlafaxine GH XR, 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 Desvenlafaxine GH XR being taken reduces the possibility of these effects occurring.

Some of these symptoms may impair driving, or the operation of dangerous machinery. Avoid these activities if you

experience any of these symptoms.

Avoid drinking alcohol while you are taking Desvenlafaxine GH XR.

Do not give this medicine to anyone else even if they have the same condition as you.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Desvenlafaxine GH XR.

All medicines can have side effects. Sometimes they are serious; often they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking this medicine, symptoms 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.

Do not be alarmed by the list of side effects.

You may not experience any of them.

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

Tell your doctor if...

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- 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...

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

- Muscle 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
- Bleeding or bruising more easily than normal
- Numbness or pins and needles.

Go to hospital if...

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- 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.

Other side effects not listed above may also occur in some people.

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. Others may occur in some people and there may be some side effects not yet known.

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

**AFTER TAKING
DESVENLAFAXINE GH
XR**

Storage

Keep your Desvenlafaxine GH XR tablets in their blister pack until it is time to take them.

The tablets may not last as well if you take them out of the blister pack.

Keep Desvenlafaxine GH XR tablets in a cool dry place where the temperature stays below 25°C.

Do not store Desvenlafaxine GH XR tablets or any other medicine in the bathroom or near a sink. Do not leave Desvenlafaxine GH XR tablets in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep Desvenlafaxine GH XR tablets and all medication 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

50mg: Light pink, biconvex, round shaped film coated tablets debossed with "DV" on one side and "50" on the other side.

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

Desvenlafaxine GH XR 50 mg and 100 mg are packed in Blister using Clear PVC/ Aclar as forming (base) material & Peel push Aluminium foil as the lidding. Blister pack of 7, 14 and 28 tablets. All packs may not be marketed.

Ingredients

Desvenlafaxine GH XR 50 mg tablets contain 50 mg of Desvenlafaxine benzoate as the active ingredient.

Desvenlafaxine GH XR 100 mg tablets contain

100 mg Desvenlafaxine benzoate as the active ingredient.

Other Ingredients

Desvenlafaxine GH XR contain Cellulose-microcrystalline, talc, stearic acid, silica colloidal anhydrous, magnesium stearate and hypromellose.

Name and Address of Sponsor

Lupin Australia Pty Ltd
Level 1, 1102 Toorak Rd
Camberwell VIC 3124,
Australia

Supplier

Generic Health Pty Ltd
Level 1, 1102 Toorak Rd
Camberwell VIC 3124,
Australia

Australian Registration Number

50 mg AUSTR No. -
227805
100 mg AUSTR No.-
227806

Date of Preparation

May 2015