

BTC DESVENLAFAXINE

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 BTC DESVENLAFAXINE?

BTC DESVENLAFAXINE contains the active ingredient desvenlafaxine. BTC DESVENLAFAXINE is used in the treatment and prevention of relapse of depression. For more information, see Section [1. Why am I using BTC DESVENLAFAXINE?](#) in the full CMI.

2. What should I know before I use BTC DESVENLAFAXINE?

Do not use if you have ever had an allergic reaction to desvenlafaxine, venlafaxine or any of the ingredients listed at the end of the CMI. Do not take BTC DESVENLAFAXINE 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.

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. BTC DESVENLAFAXINE is not recommended for use during pregnancy or breastfeeding.

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

3. What if I am taking other medicines?

Some medicines may interfere with BTC DESVENLAFAXINE and affect how it works. These include medications for depression known as monoamine oxidase inhibitors, any other medications for bipolar disorder, depression, anxiety, obsessive-compulsive disorder or pre-menstrual dysphoric disorder, ADHD, drugs that affect serotonin levels, medicines for weight loss, triptans, aspirin or NSAIDs and warfarin. 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 BTC DESVENLAFAXINE?

- Usual dose is 50 mg taken once daily with or without food. 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.

More instructions can be found in Section [4. How do I take BTC DESVENLAFAXINE?](#) in the full CMI.

5. What should I know while using BTC DESVENLAFAXINE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using BTC DESVENLAFAXINE.• Watch carefully for signs that your depression is getting worse, especially in the first few weeks of treatment or if your dose has changed.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dose without the advice of your doctor.• Do not drink alcohol while you are taking BTC DESVENLAFAXINE.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating dangerous machinery until you know how BTC DESVENLAFAXINE affects you.• BTC DESVENLAFAXINE extended release tablets may make you feel drowsy.
Looking after your medicine	<ul style="list-style-type: none">• Keep BTC DESVENLAFAXINE extended release tablets in a cool dry place where the temperature stays below 25°C. Keep tablets in their blister pack until it is time to take them.

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

6. Are there any side effects?

Common side effects of BTC DESVENLAFAXINE include stomach, bowel or urinary tract problems (e.g. nausea, diarrhoea, constipation, difficulty passing urine), change in behaviour (e.g. difficulty/abnormal sleeping, anxiety, irritable), difficulty in thinking or working (due to yawning, disturbed concentration, fainting/dizziness, fatigue), excessive sweating, hot flushes, rash, weight gain/loss or changes to sensory (vision, hearing, taste). Seek emergency treatment if you experience symptoms of neuroleptic malignant syndrome or serotonin syndrome.

Tell your doctor immediately if you experience negative changes to mood or behaviour, worsening depression including thoughts of suicide.

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.

BTC DESVENLAFAXINE

Active ingredient(s): *Desvenlafaxine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BTC DESVENLAFAXINE. **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 BTC DESVENLAFAXINE.**

Where to find information in this leaflet:

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

1. Why am I using BTC DESVENLAFAXINE?

BTC DESVENLAFAXINE contains the active ingredient desvenlafaxine.

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. BTC DESVENLAFAXINE extended release tablets increase the level of these two messengers. Experts think this is how it helps to restore your feeling of wellness.

BTC DESVENLAFAXINE 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 BTC DESVENLAFAXINE has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use BTC DESVENLAFAXINE?

Warnings

Do not use BTC DESVENLAFAXINE if:

- You are allergic to desvenlafaxine, venlafaxine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- 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.

Check with your doctor if you have:

- Other medications that you are taking
- 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.

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.

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

BTC DESVENLAFAXINE is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of taking BTC DESVENLAFAXINE if you are pregnant. One of these risks is that newborn babies whose mothers have been taking BTC DESVENLAFAXINE may have several problems including breathing difficulties, rapid breathing, seizures, lack of oxygen in their blood, physical and / or behavioural problems, vomiting and diarrhoea.

If you take BTC DESVENLAFAXINE or similar antidepressants mid to late in your pregnancy, you may develop a condition known as "pre-eclampsia", which is characterised by persistent high-blood pressure during or after pregnancy. Symptoms of pre-eclampsia can include headaches, abdominal pain, shortness of breath or burning behind the sternum, nausea and vomiting, confusion, heightened state of anxiety, and/or visual disturbances such as oversensitivity to light, blurred vision, or seeing flashing spots or auras.

If you take BTC DESVENLAFAXINE or similar antidepressants in the last month of your pregnancy, you may experience heavy bleeding during and/or after delivery.

Continuing treatment with BTC DESVENLAFAXINE or similar antidepressants during pregnancy should be strictly as directed by your doctor. Symptoms of a relapse may

occur if treatment is discontinued, even if major depression was previously under control.

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

BTC DESVENLAFAXINE passes into breast milk and there is a possibility that the breast-fed baby may be affected. For this reason, the use of BTC DESVENLAFAXINE is not recommended in breast-feeding women.

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 such as St John's wort or tryptophan supplements.

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

Some medicines may interfere with BTC DESVENLAFAXINE and affect how it works. These include:

- Medications for depression known as monoamine oxidase inhibitors (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 BTC DESVENLAFAXINE or medicines similar to BTC DESVENLAFAXINE with monoamine oxidase inhibitors or within 14 days of taking a monoamine oxidase inhibitor 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 used to treat Attention Deficit Hyperactivity Disorder (ADHD) such as dexamphetamine and lisdexamphetamine
- Medicines for weight loss, including sibutramine
- Triptans (used to treat migraine)
- Linezolid (used to treat infections)
- Drugs that affect your tendency to bleed (e.g. Aspirin, NSAIDS, Warfarin)
- Opioids (used to manage pain)

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 BTC DESVENLAFAXINE.

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

4. How do I take BTC DESVENLAFAXINE?

How much to take

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

The maximum dose should not exceed 200 mg per day.

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 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 BTC DESVENLAFAXINE.

Follow the instructions provided and use BTC DESVENLAFAXINE until your doctor tells you to stop.

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

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 long to take BTC DESVENLAFAXINE

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 BTC DESVENLAFAXINE time to work.

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

When to take BTC DESVENLAFAXINE

Take BTC DESVENLAFAXINE 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.

If you forget to use BTC DESVENLAFAXINE

BTC DESVENLAFAXINE should be used regularly at the same time each day.

If you miss your dose and if it is less than 12 hours until your next dose, 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 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 use too much BTC DESVENLAFAXINE

If you think that you have used too much BTC DESVENLAFAXINE, you must seek urgent medical attention.

You should immediately:

- Phone the Poisons Information Centre (by calling **13 11 26**), 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.

5. What should I know while using BTC DESVENLAFAXINE?

Things you should do

Visit your doctor regularly for a checkup so that your progress can be checked. Always discuss any questions you have about BTC DESVENLAFAXINE with your doctor.

Take BTC DESVENLAFAXINE extended release tablets as your doctor has prescribed.

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

Keep enough BTC DESVENLAFAXINE extended release 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 BTC DESVENLAFAXINE.

Call 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
- Confusion
- Hallucination (seeing or hearing things)
- Aggressiveness
- Hostility or impulsiveness
- Restlessness
- Unusual/involuntary muscle movements (e.g., hyper-reflex or blurred vision)
- Irregular/high blood pressure, irregular/increased heart rate and/or fever
- Overactivity or uninhibited behaviour
- Other unusual changes in behaviour
- Worsening depression

- Thoughts of suicide.

High fever, stiffness of the muscles, altered mental status (paranoid behaviour) and autonomic dysfunction (wide swings of blood pressure, excessive sweating and excessive saliva) may be signs of something called neuroleptic malignant syndrome.

Headache, shivering, diarrhoea, muscle stiffness, high fever and seizures may be signs of something called serotonin syndrome.

Neuroleptic malignant syndrome and serotonin syndrome are serious and may be life-threatening. Symptoms of neuroleptic malignant syndrome or serotonin syndrome can vary, if you think you might have either of these syndromes while taking BTC DESVENLAFAXINE, call your doctor immediately or go to the emergency department of nearest hospital. If you have severe or rapidly worsening symptoms, seek emergency treatment immediately.

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 who is taking BTC DESVENLAFAXINE, shows 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 should not do

Do not stop using this medicine 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 BTC DESVENLAFAXINE to help avoid side effects. Side effects are known to occur when people stop taking BTC DESVENLAFAXINE, especially when they suddenly stop therapy.

Some of these side effects include:

- Headache
- Nausea
- Dizziness
- Tiredness
- Irritability
- Anxiety
- Abnormal dreams
- Diarrhoea
- Excessive sweating
- Visual impairment
- High blood pressure

Slowly reducing the amount of BTC DESVENLAFAXINE being taken reduces the possibility of these effects occurring.

In some people this may need to occur over periods of months or longer.

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

Do not give this medicine to anyone else even if 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 BTC DESVENLAFAXINE affects you.

BTC DESVENLAFAXINE may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not drink alcohol while you are taking BTC DESVENLAFAXINE.

Looking after your medicine

Keep your BTC DESVENLAFAXINE extended release 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.

Store it in a cool (below 25°C) 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.

Heat and dampness can destroy some medicines.

Keep BTC DESVENLAFAXINE extended release tablets and all medication where young children cannot reach it.

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

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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.

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.

Side effects

Side effects	What to do
<ul style="list-style-type: none"> • Stomach, bowel or urinary tract problems: <ul style="list-style-type: none"> ○ Nausea or vomiting ○ Loss of appetite ○ Diarrhoea ○ Constipation ○ Difficulty passing urine • Changes in your behaviour: 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

<ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ○ Yawning ○ Disturbances in concentration ○ Fainting or dizziness after standing up ○ Fatigue ○ Rapid heartbeat ○ Chills ○ Headache • Excessive sweating • Hot flushes • Rash • Weight loss • Weight gain • Blurred vision • Ringing in the ears • Altered taste, dry mouth. 	
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Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. 	<p>Call your doctor as soon as possible.</p>
<ul style="list-style-type: none"> • Palpitations, shortness of breath, intense chest pain, or irregular heartbeats • Severe upper abdominal pain • Swollen and tender abdomen • Fever 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest</p>

<ul style="list-style-type: none"> Rise or decrease in blood pressure. You may experience headache, blurred vision, palpitations, confusion or loss of consciousness. Sometimes you may not experience any of these symptoms. It is important to keep your routine doctor's appointments so that your blood pressure can be checked 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. 	<p>hospital if you notice any of these serious side effects.</p>
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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.

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.

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 BTC DESVENLAFAXINE contains

Active ingredient (main ingredient)	desvenlafaxine
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Alginic Acid Citric Acid Monohydrate Hypromellose Microcrystalline cellulose Povidone Purified talc Magnesium stearate

	<ul style="list-style-type: none"> OPADRY complete film coating system 03F84770 PINK (50 mg tablet only) OPADRY complete film coating system 03F86990 BROWN (100 mg tablet only).
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Do not take this medicine if you are allergic to any of these ingredients.

BTC DESVENLAFAXINE does not contain gluten

What BTC DESVENLAFAXINE looks like

There are two strengths of BTC DESVENLAFAXINE extended release tablets:

- The 50 mg tablet is a Light pink colored, diamond shaped, biconvex tablets, debossed with '111' on one side and plain on other side.
- The 100 mg tablet is a Dark brown to red colored, diamond shaped, biconvex tablets, debossed with '171' on one side and plain on other side.

Each carton contains 28 tablets.

Who distributes BTC DESVENLAFAXINE

Sandoz Pty Ltd

100 Pacific Highway

North Sydney, NSW 2060

Australia

Tel 1800 726 369

Australian Registration Numbers:

BTC DESVENLAFAXINE 50 mg tablets - AUST R 425290

BTC DESVENLAFAXINE 100 mg tablets - AUST R 425291

This leaflet was prepared in February 2026.