

# Pristiq®

Desvenlafaxine Succinate Extended Release Tablets

## Consumer Medicine Information

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### What is in this leaflet

This leaflet answers some common questions about Pristiq tablets. 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 Pristiq against the expected benefits it will have for you.

If you have any questions about Pristiq, ask your doctor or pharmacist.

Keep this leaflet with your Pristiq tablets. You may need to read it again.

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### What Pristiq is for

The name of your medicine is Pristiq. It contains the active ingredient called desvenlafaxine succinate.

Pristiq is used in the treatment 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.

Pristiq tablets belong to a class of medications called Serotonin-Noradrenaline Reuptake Inhibitors (SNRIs).

Pristiq is not addictive.

Your doctor may have prescribed Pristiq tablets for another purpose.

Ask your doctor if you have any questions about why Pristiq tablets has been prescribed for you.

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### Before you take Pristiq

#### **When you must not take Pristiq**

Do not take Pristiq if you are taking other medications for depression known as monoamine oxidase inhibitors, even if you have stopped taking them now, but have taken them within the last 14 days.

Do not take Pristiq 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 Pristiq to children or adolescents under 18 years of age.

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

Do not use Pristiq after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well as it should.

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

### **Before you start to take Pristiq**

Tell your doctor or pharmacist if you have allergies to desvenlafaxine, venlafaxine or any of the other ingredients listed at the end of this leaflet.

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

Pristiq is not recommended for use during pregnancy. Your doctor will discuss the risks and benefits of using Pristiq if you are pregnant. One of these risks is that newborn babies whose mothers have been taking Pristiq 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 planning to breast-feed.

Pristiq passes into breast milk and there is a possibility that the breast-fed baby may be affected. For this reason, the use of Pristiq 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 take Pristiq.

### **Taking other medicines**

Tell your doctor or pharmacist if you take any other medicines, including any that you buy without a prescription from a 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 Pristiq, unless it is prescribed or approved by your doctor.

Some medicines may interfere with Pristiq or Pristiq may interfere with these medicines. These include:

- Medications for depression known as monoamine oxidase inhibitors (such as phenelzine and tranylcypromine), even if you have stopped taking them now, but have taken them within the last 14 days. 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 premenstrual dysphoric disorder, including St John's Wort
- Medicines for weight loss, including sibutramine
- Triptans (used to treat migraine)
- Tramadol (a pain killer)
- Linezolid (used to treat infections).

You may need to use 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 Pristiq.

### **Switching to Pristiq from other antidepressants**

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

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## **How to take Pristiq**

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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 Pristiq.

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**

For the treatment of depression, the usual dose is 50 mg taken once daily.

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

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

### **When to take it**

**Pristiq should be taken once daily with food, at approximately the same time each day.**

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

Avoid drinking alcohol while you are using Pristiq.

### **How long to take Pristiq**

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 Pristiq time to work.

Even when you feel well again, you may need to keep taking Pristiq for several months. Discuss this with your doctor and don't stop taking Pristiq until gaining your doctor's agreement.

### **If you forget to take Pristiq**

If you miss a dose, take it as soon as you remember.

However, if it is almost time for your next dose, skip the missed dose.

Don't try to "make up" for the missed dose by taking two doses at the same time.

Do not take more than the prescribed daily amount of Pristiq.

If you take more Pristiq than the amount prescribed, contact your healthcare professional immediately.

Always finish the tablets you are taking in the current pack before you start a new pack.

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

### **If you take too much (overdose)**

It is important that you do not take more Pristiq tablets than your doctor has prescribed. If you do take more than you have been prescribed, contact your doctor immediately for advice.

If anyone accidentally swallows any Pristiq tablets, call your nearest Poisons Information Centre for advice (tel: 13 11 26), or go to Accident and Emergency at your nearest hospital. Keep the telephone number for these places handy whilst taking any medications.

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## While you are taking Pristiq

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### **Things you must do**

Visit your doctor regularly for a check up. Always discuss any questions you have about Pristiq tablets with your doctor.

Take Pristiq tablets as your doctor has prescribed.

Keep enough Pristiq tablets to last weekends and holidays. You need a prescription from your doctor to get more Pristiq tablets.

If you are taking Pristiq for depression, watch carefully for signs that your depression is getting worse, especially in the first few weeks of treatment or if your dose has changed.

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:**

All thoughts or talk about suicide or violence are serious. If you or someone you know is showing the following warning signs, either contact your doctor or a mental health advisor right away or go to the nearest hospital for treatment:

- 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**

Pristiq tablets may make you feel drowsy. Be careful driving or operating dangerous machinery until you know how it affects you.

### **Things you must not do**

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

Your doctor may want to slowly decrease your dose of Pristiq to help avoid side effects. Side effects are known to occur when people stop using Pristiq, 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 Pristiq 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 these symptoms.**

Ask your doctor for advice if any of these side effects become troublesome.

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

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## Side effects

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All medicines can have side effects. Sometimes they are serious; often they are not.

Tell your doctor if you develop any of the following side effects or if they become troublesome.

Stomach, bowel or urinary tract problems such as:

- Nausea or vomiting
- Loss of appetite
- Diarrhoea
- Constipation
- Difficulty passing urine.

Changes in your behaviour such as:

- 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
- Muscle stiffness or movement disorders
- A feeling of apathy or not caring about things
- Feeling detached from yourself
- Seizures.

Difficulty thinking or working because of:

- Yawning
- Disturbances in concentration
- Fainting or dizziness after standing up
- Muscle weakness
- Fatigue
- Rapid heart beat
- Chills
- Headache.

Changes in your appearance such as:

- Excessive sweating
- Hot flushes
- Rash
- Weight loss or weight gain

- Bleeding or bruising more easily than normal.
- Swelling of the face, lips, tongue, throat or other parts of the body

Changes in your sight, hearing, taste or touch such as:

- Blurred vision
- Dilated pupils
- Visual disturbances
- Ringing in the ears
- Altered taste
- Dry mouth
- Numbness or pins and needles.

Other changes you may not be aware of:

- Increased blood pressure
- Changes in blood tests for liver function
- Occurrences of protein in the urine
- Increase in blood cholesterol levels.

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 else that is making you feel unwell, even if it is not on this list.

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## After using Pristiq

### Storage

Keep your Pristiq 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 Pristiq tablets in a cool dry place where the temperature stays below 25°C.

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

Heat and dampness can destroy some medicines.

Keep Pristiq 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

Return any unused medicine to your pharmacist.

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## Product Description

### What Pristiq looks like

There are two strengths of Pristiq tablets, containing 50 mg or, 100 mg of desvenlafaxine in an extended release formulation, which allows for once-a-day dosing.

Tablets come in different colours, depending on their strengths:

- The 50 mg tablet is a light pink, square pyramid tablet debossed with "W" (over) "50" on the flat side.
- The 100 mg tablet is a reddish-orange, square pyramid tablet debossed with "W" (over) "100" on the flat side.

Pristiq 50 mg and 100 mg are available in cartons containing 28 tablets.

### Ingredients

Pristiq tablets contain desvenlafaxine succinate as the active ingredient.

Pristiq 50 mg and 100 mg tablets contain the following inactive ingredients:

- Cellulose-microcrystalline
- Hypromellose
- Talc, purified
- Magnesium stearate
- Carboxymethylcellulose sodium
- Maltodextrin
- Glucose
- Titanium dioxide
- Stearic acid

- Red iron oxide.

Pristiq 100 mg tablets also contain black iron oxide.

### Supplier

Wyeth®

Pristiq tablets are supplied by:

Wyeth Australia Pty Limited

ABN: 16 000 296 211

17-19 Solent Circuit,

Norwest Business Park,

Baulkham Hills, NSW 2153.

For further information please contact Wyeth Australia on toll-free 1800 500 498 or E-mail: [medinfo@wyeth.com](mailto:medinfo@wyeth.com)

### Australian Registration Numbers:

Pristiq 50 mg tablets:

AUST R 133520

Pristiq 100 mg tablets:

AUST R 133527

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