

Prexaton

Bupropion hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you start taking Prexaton.

This leaflet answers some common questions about Prexaton.

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

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

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Prexaton is used for

Prexaton contains an active ingredient called "bupropion hydrochloride". It is believed that it interacts with chemicals called noradrenaline and dopamine in the brain, however the exact mechanism of action is not fully understood.

Prexaton is a medicine prescribed by your doctor as a short-term treatment to help you stop smoking with appropriate counselling. For many patients, Prexaton reduces withdrawal symptoms and the urge to smoke.

Your doctor may have prescribed Prexaton for another reason.

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

There is no evidence showing that Prexaton is addictive.

Before you take Prexaton

You should be fully committed to quitting smoking before you start to take Prexaton.

You are more likely to quit smoking if you have appropriate support. You should tell your family, friends and work colleagues that you are trying to quit smoking so that they can offer you support and encouragement.

When you must not take it

Do not take Prexaton if:

- * **You have ever had an allergic reaction to Prexaton, bupropion or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.

Allergic reactions can last a long time. Talk to your doctor about the management of the allergic symptoms.

- * **You now have or you have ever had a seizure disorder or 'fit' (e.g. epilepsy)**
- * **You are usually a heavy drinker but you have suddenly stopped drinking alcohol or you plan to do so while taking Prexaton.**
- * **You have suddenly stopped taking tranquillizers or you plan to do so while taking Prexaton.**
- * **You have a brain tumour.**
- * **You are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using Prexaton if you are pregnant or breastfeeding.

- * **You are taking a medicine called a Monoamine Oxidase Inhibitor (MAOI), or have taken a Monoamine Oxidase Inhibitor in the last 14 days.**
- * **You have ever had an eating disorder (eg. bulimia or anorexia nervosa)**
- * **The tablets have passed the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**
If your medicine 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 are allergic to foods, dyes, preservatives or any other medicines.**
- * **You are currently taking or have recently taken a monoamine oxidase inhibitor (MAOI).**
- * **You are currently taking a herbal preparation called St John's Wort.**
- * **You are taking medicines that suppress your appetite.**
- * **You have had a head injury.**
- * **You have liver or kidney problems.**
- * **You have any mental disorder particularly bipolar disorder (also known as manic depression).**
- * **You suffer from diabetes.**
- * **You had a seizure (fit) while taking a previous course of Prexaton.**
- * **You take a lot of medication ('sedatives') to treat anxiety.**
- * **You are a heavy drinker.**

It is best to not drink alcohol at all or to drink very little while taking Prexaton.

If you drink a lot of alcohol or suddenly stop, you may increase your chance of having a seizure. Therefore, it is important to discuss your use of alcohol with your doctor before you begin taking Prexaton.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop. These include:

- * medicines to treat malaria#
- * tramadol, a pain killer#
- * theophylline, a medicine used to treat asthma#
- * medicines that suppress your appetite#

- * medicines used to treat colds or allergies containing sedating antihistamines#
 - * antibiotics belonging to the quinolone class#
 - * steroid tablets and injections#
 - * medicines used to treat depression or schizophrenia#
 - * medicines used to treat epilepsy or fits, such as carbamazepine, phenobarbital, phenytoin and valproate
 - * medicines used to treat Parkinson's disease, such as levodopa and amantadine.
 - * medicines used to prevent stroke, to treat heart conditions or high blood pressure
 - * certain medicines used to treat cancer
 - * orphenadine, a muscle relaxant
 - * nicotine patches or gums.
- Using Prexaton and nicotine replacement therapy (i.e. nicotine patches or nicotine gum) together may raise your blood pressure. Your doctor will probably want to check your blood pressure regularly to make sure that it stays within acceptable levels.

These medicines may be affected by Prexaton or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

These medicines may increase the chance of you having a seizure or fit. Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Use in children

Prexaton tablets are not recommended for use in children less than 18 years.

How to take Prexaton

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

They may differ from the information contained in this leaflet.

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

How much to take

The course of Prexaton tablets consists of two prescriptions: an initial prescription of 30 tablets followed by a second prescription for 90 tablets.

Your first prescription of 30 tablets will last you approximately 14 days.

It is vital that you obtain the second prescription of 90 tablets and have it ready before you run out of tablets from your first prescription.

Your doctor will tell you how many tablets to take and how often to take them. You will also find this information on the label of your medicine.

If you do find your sleep disturbed, try not to take Prexaton immediately before bedtime. If you take 2 tablets, take one early in the morning and one late in the afternoon. Leave 8 hours between tablets.

First prescription

The first prescription for Prexaton is for 30 tablets. This represents slightly more than 2 weeks supply of the tablets.

Take your medicine as your doctor has told you. The usual recommended dose is one 150mg tablet each day for the first 3 days. On the fourth day, begin taking one 150mg tablet twice daily. Doses should be taken at least 8 hours apart.

You need to visit your doctor for the second prescription of tablets before you run out of tablets from the first prescription.

Second prescription

The second prescription for Prexaton is for 90 tablets. This represents slightly more than 6 weeks supply of the tablets.

Take your medicine as your doctor has told you. The usual recommended dose is one 150mg tablets twice daily. Doses should be taken at least 8 hours apart.

Do not take more tablets than your doctor has prescribed. This is important so you do not increase your chance of having a seizure (fits or convulsions).

Your doctor will advise you how to take the tablets if you have liver disease.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew, divide, or crush the tablets.

If you do, the medicine will be released into your body too quickly. If this happens you may be more likely to get side effects including seizures (fits).

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that 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.

How long to take it for

It takes about 1 week for Prexaton to reach the right levels in your body to be effective. So, to maximise your chance of stopping, you should not stop smoking until you have been taking Prexaton for 1 week. You should set a date to stop smoking during the second week you're taking Prexaton.

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

Most people should take Prexaton for at least 7 weeks.

The Pharmacist's label on the pack will tell you how to take Prexaton tablets. If there is something you do not understand, ask your doctor or pharmacist.

Prexaton and nicotine replacement therapy (i.e. nicotine patches or nicotine gum) should only be used together under the supervision of your doctor.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Prexaton. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking Prexaton

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Prexaton.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

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.

Minimise or avoid drinking alcohol when you are on Prexaton treatment.

Things you must not do

Do not take Prexaton to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine or change the dose without checking with your doctor.

Things to be careful of

Some people become depressed when they try to stop smoking; very occasionally, they may think about committing suicide, or try to do so. These symptoms have also affected people taking Prexaton for smoking cessation.

Bupropion, the active ingredient in Prexaton is also used for treatment of depression. People taking antidepressants sometimes have thoughts of harming or killing themselves. These thoughts may be increased when they first start taking them.

If you feel depressed or think about suicide, get medical advice as soon as possible.

Be careful driving or operating machinery until you know how Prexaton affects you.

As with many other medicines, Prexaton may cause dizziness, drowsiness, tiredness, altered concentration or visual disturbance in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you have any problems while taking Prexaton, even if you do not think the problems are connected with the medicine or are not listed in this

leaflet.

Like other medicines, Prexaton may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists 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 or pharmacist if you notice any of the following and they worry you:

- * headache
- * difficulty sleeping (see 'How to take Prexaton tablets')
- * dry mouth
- * upset stomach (e.g. nausea and constipation).

The above list includes the more common side effects of your medicine.

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

- * fever
- * tiredness
- * flushing
- * shakiness
- * anorexia
- * ringing in the ears
- * impaired vision
- * taste disorder
- * changes in mood
- * difficulty in concentrating
- * irritability
- * hostility
- * agitation
- * hallucinations
- * delusions
- * paranoid thoughts
- * anxiety
- * dizziness
- * fluttering of the heart rate
- * tingling or numbness
- * loss of memory
- * changes in blood sugar levels

- * an increase in blood pressure may be recorded which in some cases can be severe.

The above list includes serious side effects that may require medical attention.

If you think you are having an allergic reaction to Prexaton tablets, TELL YOUR DOCTOR IMMEDIATELY or go to Accident and Emergency at your nearest hospital. Symptoms usually include some or all of the following:

- * wheezing
- * swelling of the lips/mouth
- * difficulty in breathing
- * hay fever
- * lumpy rash ("hives")
- * fainting.

There is a chance that approximately 1 out of every 1000 people taking bupropion hydrochloride, the active ingredient in Prexaton, will have a seizure. The chance of this happening increases if you:

- * have or have had a seizure disorder (for example, epilepsy);
- * have or have had an eating disorder (for example, bulimia or anorexia nervosa);
- * take more than the recommended amount of Prexaton;
- * are taking any other medicine containing bupropion;
- * have had a head injury;
- * are a heavy drinker; or
- * suffer from diabetes.

Other medication may increase the chance of you having a seizure.

Refer to the "Taking other medicines" section.

You can reduce the chance of experiencing a seizure by giving your doctor the information he needs and following carefully your doctor's directions on how to take Prexaton.

Effects of stopping smoking

People giving up smoking are often affected by nicotine withdrawal. Similar effects have also been

reported in Prexaton users undergoing a smoking cessation attempt. These may include

- * difficulty sleeping, tremor or sweating
- * agitation or feelings of depression (sometimes with thoughts of suicide).

If you feel any worrisome changes of mood, talk to your doctor immediately.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell, even if it is not on this list.

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

After taking Prexaton

Storage

Keep this medicine 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.

Keep your tablets in a cool, dry place where they stay below 25 degrees C.

Do not store Prexaton or any other medicine in a bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

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

Australian registration number:
AUST R 119661

What it looks like

Prexaton tablets are white, film-coated biconvex, round tablets coded 'GX CH7'.

Prexaton tablets are supplied in foil blisters. The foil blisters contain 30 and 90 tablets, for oral use only, and they are in a carton.

This leaflet was prepared on
5 June 2008.

Ingredients

Prexaton tablets contain 150 mg of the active ingredient bupropion hydrochloride.

They also contain the following inactive ingredients:

- * microcrystalline cellulose
- * hypromellose
- * cysteine hydrochloride
- * magnesium stearate
- * macrogol
- * titanium dioxide (E171)
- * carnauba wax
- * edible black ink.

This medicine does not contain lactose.

Prexaton tablets may have a characteristic odour. If present, this odour is normal.

Supplier

Prexaton is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

For further information please contact Medical Information on toll-free phone:
1800 028 365