

EXTINE

contains the active ingredient paroxetine (as hydrochloride)



CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about EXTINE.

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 EXTINE 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 EXTINE is used for

EXTINE is used to:

- treat depression
- treat irrational fears or obsessional behaviour
- prevent panic attacks
- treat patients who avoid or are fearful of social situations
- treat patients with excessive anxiety and worry, and who feel irritable, restless, and/or tense in the muscles
- treat repetitive and distressing recollections of a past traumatic event.

Depression is longer lasting or more severe than the 'low moods' that everyone has from time to time. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms. You may feel low in spirit, lose interest in usual activities, be unable to enjoy life, have poor appetite or over eat, have disturbed sleep, often wake up early, have low energy and feel guilty over nothing. EXTINE corrects the

chemical imbalance and so helps relieving the symptoms of depression.

EXTINE belongs to a group of medicines called selective serotonin reuptake inhibitor (SSRI) antidepressants. They are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

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

EXTINE is not recommended to treat depression in children and adolescents under 18 (see **Use in children and adolescents**).

EXTINE is available only with a doctor's prescription.

Before you take EXTINE

Antidepressants can increase suicidal thoughts and actions in some children and adolescents younger than 18 years of age. But suicidal thoughts and actions can also be caused by depression, a serious medical condition that is commonly treated with antidepressants. Thinking about killing yourself or trying to kill yourself is called suicidality or being suicidal.

Antidepressants are used to treat depression and other illnesses. Depression and other illnesses can lead to suicide. In some children and adolescents, treatment with an antidepressant increases suicidal thinking or actions. It is important to discuss all the risks of treating depression and also the risks of not treating it. You should discuss all treatment choices with your doctor, not just the use of antidepressants.

Patients (and caregivers of patients) need to monitor for any worsening of their condition and/or the emergence of thoughts of suicide or suicidal behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present. (See **Use in children and adolescents**).

When you must not take it

Do not take EXTINE if you are allergic to medicines containing paroxetine or any of the ingredients listed at the end of this leaflet.

Do not take EXTINE if you are pregnant or intend to become pregnant.

Studies show that the use of paroxetine in early pregnancy (first 13 weeks) may be associated with an increased risk of some birth defects in babies. If you become pregnant or intend to become pregnant while taking paroxetine, you should make an appointment to see your doctor and have your treatment reviewed. It is important that you do not stop taking paroxetine suddenly. Paroxetine is a medicine that can have withdrawal side effects if stopped suddenly (see **Unwanted Effects that may occur on stopping treatment**).

Do not take EXTINE if you have taken paroxetine before and you became unwell. Tell your doctor or pharmacist before taking the first dose.

Do not take EXTINE if you have taken any other medications for the treatment of depression in the last two weeks.

Taking EXTINE with another antidepressant may cause a serious reaction. You must not take EXTINE until 2 weeks after stopping monoamine oxidase inhibitor drugs (MAOIs). Examples of MAOIs are phenelzine (Nardil) and

tranylcypromine (Parnate). There may be others, so please check with your doctor. Taking EXTINE with a MAOI may cause a serious reaction.

Do not take EXTINE if you are taking thioridazine (Melleril, Aldazine) for the treatment of schizophrenia.

Do not take EXTINE if you are taking pimozide (Orap).

Do not take EXTINE if the expiry date (Exp.) printed on the pack has passed.

Do not take EXTINE if the packaging shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking EXTINE when breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- liver problems
- heart problems
- kidney problems
- epilepsy
- mania
- raised pressure in the eye
- blood clotting problems
- other psychiatric conditions (eg bipolar disorder).

If you have not told your doctor about any of the above, tell him/her before you start taking EXTINE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by EXTINE, or may affect how well it works. These include:

- any other medicines used to treat depression, anxiety or schizophrenia including medicines you buy without a doctor's prescription such as tryptophan or *Hypericum perforatum* (St John's wort)
- medicines to lower blood pressure or treat heart conditions, such as metoprolol (Betaloc), flecainide (Tambacor), digoxin (Lanoxin)
- medicines to control epilepsy (anti-convulsants), such as phenytoin (Dilantin)
- medicines to thin the blood such as warfarin (Coumadin, Marevan), aspirin (Aspro)
- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis (NSAIDs)
- medicines to treat Parkinson's disease such as selegiline (Eldepryl), procyclidine (Kemadrin)
- medicines to treat stomach ulcers, such as cimetidine (Tagamet)
- medicines to treat migraine attacks such as sumatriptan.
- medicines to treat HIV infection, such as fosamprenavir (Telzir), ritonavir (Norvir)
- tramadol, a medicine used to relieve pain.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking EXTINE.

Some combinations of medicines may increase the risk of serious side effects and are potentially life-threatening.

How to take EXTINE

How much to take

Your doctor will tell you how many tablets you need to take each day

and when to take them. This depends on your condition and whether or not you are taking any other medicines.

The usual dose of EXTINE for depression, social anxiety disorder/social phobia, generalised anxiety disorder or post-traumatic stress disorder is one 20 mg tablet per day. Your doctor may increase the dose slowly over several weeks.

To treat obsessions and compulsions or panic attacks, the usual dose of EXTINE is two 20 mg tablets per day. Your doctor may start you on a lower dose and increase the dose slowly over several weeks.

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

How to take EXTINE

Swallow the tablets with a glass of water or other liquid. EXTINE tablets can be broken in half, but should not be chewed.

EXTINE should be taken in the morning, preferably with food.

If you forget to take EXTINE

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

If you are not sure what to do, ask your doctor or pharmacist.

How long to take EXTINE for

Keep taking EXTINE for as long as your doctor tells you.

Like other drugs of this type, EXTINE will not relieve your

symptoms straight away. You should start to feel better after a week or two, although it may take longer.

Occasionally the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full anti-depressant effect of your medicine becomes apparent (i.e. one to two months).

You or anyone close to you or caring for you should watch for these symptoms and tell your doctor immediately or go to the nearest hospital if you have any distressing thoughts or experiences during this initial period or at any other time.

Also contact your doctor if you experience any worsening of your depression or other symptoms at any time during your treatment.

Stopping treatment

Do not stop taking EXTINE even if you begin to feel better.

Your doctor may decide that you should continue to use EXTINE for some time, even when you have overcome your problem. For best effect, EXTINE must be taken regularly. Your doctor will tell you when and how EXTINE should be discontinued.

Your doctor will usually recommend that you stop treatment by slowly reducing the dosage over a period of several weeks. When you stop treatment with EXTINE, especially if this is done suddenly, you may experience unwanted symptoms. Please see the section of this leaflet under "***Unwanted Effects that may occur on stopping treatment***".

If you take too much EXTINE (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or

anyone else may have taken too much EXTINE. Do this even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

Use in children and adolescents

EXTINE is not recommended to treat depression in children and adolescents under 18, as the medicine has not been shown to be effective in this age group and there are possible unwanted effects.

Information from clinical trials has suggested that young adults, particularly those with depression, may be at an increased risk of suicidal behaviour (including suicide attempts) when treated with paroxetine. The majority of attempted suicides in clinical trials in depression involved patients aged 18 to 30 years.

Family and caregivers of children and adolescents being treated with antidepressants for major depressive disorder or for any other condition (psychiatric or non-psychiatric) need to monitor them for the emergence of agitation, irritability, unusual changes in behaviour, as well as the emergence of thoughts of suicide, and to report such symptoms immediately to their doctor. It is particularly important that monitoring be undertaken during the initial few months of antidepressant treatment or at times of dose increase or decrease.

While you are taking EXTINE

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking EXTINE.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking EXTINE.

If you become pregnant while taking EXTINE, tell your doctor.

People taking EXTINE may be more likely to think about killing themselves or actually try to do so, especially when EXTINE is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using EXTINE who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse during the first one to two months of taking EXTINE until the medicine starts to work completely. This is more likely to occur if you are a young adult, i.e. 18 to 24 years of age, and you have not used antidepressant medicines before.

If you or someone you know or care for demonstrates any of the following warning signs of suicide-related behaviour while taking EXTINE, contact a doctor immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts of talk of self-harm or harm to others
- any recent attempts of suicide or self-harm
- increase in aggressive behaviour, irritability or agitation
- worsening of depression.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Visit your doctor regularly so he/she can check on your progress.

Things you must not do

Do not stop taking EXTINE, or lower the dose, without checking with your doctor.

When your doctor decides that you should stop taking EXTINE, the dose may be reduced slowly or the time between doses increased over 1 or 2 weeks. Stopping EXTINE suddenly may cause dizziness, anxiety, sleep disturbances, pins and needles, electric shock sensations, nausea and sweating. Your doctor may want you to gradually reduce the amount of EXTINE you are taking before stopping completely.

Although EXTINE is not recommended for use in children under 18 years of age, additional symptoms that have been experienced by children whilst stopping treatment are abdominal pain, nervousness and mood changes.

Do not use EXTINE to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

EXTINE may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Although drinking moderate amounts of alcohol is unlikely to affect your response to EXTINE, it is best to avoid alcohol while you are taking this medicine.

Side effects

Tell your doctor or pharmacist as soon as possible if you do

not feel well while you are taking EXTINE.

Like all other medicines, EXTINE may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible 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 you notice any of the following and they worry you:

- feeling sick
- dry mouth
- decreased appetite
- diarrhoea, constipation
- drowsiness or dizziness
- difficulty falling asleep
- impaired sexual function
- weakness
- feeling sweaty or shaky
- bruising
- weight gain.

Tell your doctor immediately if you notice any of the following:

- muscle spasm or twitches.

Stop taking EXTINE and tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following soon after taking EXTINE:

- allergic reactions including swelling of limbs, face, lips, mouth or throat which may cause difficulty in swallowing or breathing. Hayfever, lumpy rash (hives) or fainting are also symptoms of an allergic reaction
- sudden onset of prolonged muscle spasm, affecting the eyes, head neck and body
- sudden increase in body temperature, severe convulsions
- fast heart beat, sweating, muscle spasm, racing thoughts, restlessness.

Other rare events that may occur are:

- blurred vision
- abnormal liver function
- low levels of sodium in the blood, especially in older people
- bleeding disorders
- hormone disturbances
- mood of excitement, over-activity and uninhibited behaviour
- confusion
- seizures
- rash caused by exposure to light
- akathisia (restlessness or difficulty keeping still, caused by medicines to treat mental disorders).

Unwanted Effects that may occur on stopping treatment:

Symptoms may include:

- dizziness
- sensory disturbances such as tinnitus, pins and needles, burning sensations and electric shock-like sensations
- sleep disturbances, including intense dreams
- agitation or anxiety
- feeling sick
- shaking or tremors
- confusion
- sweating
- headache
- diarrhoea.

These are likely to occur in the first few days of stopping treatment or very rarely if you miss a dose. However, they are more likely to occur if you stop taking EXTINE too quickly. Therefore, always consult your doctor before stopping your medicine. For the majority of patients, symptoms go away on their own within a few weeks. However, if you feel that the unwanted symptoms are too severe, see your doctor who will suggest how to manage stopping treatment more slowly.

Additional symptoms that have been experienced by children whilst stopping treatment are changing emotions (including thoughts of suicide, attempting suicide, mood changes and feeling tearful), abdominal pain and nervousness.

Although EXTINE is not recommended for children under the age of 18 years of age, the

most common unwanted effects in children under 18 are:

- decreased appetite
- tremor (uncontrollable trembling)
- sweating
- hyperactivity
- hostile/unfriendly behaviour
- agitation
- changing emotions, including crying, changes in mood, trying to harm themselves, thought of suicide and attempting suicide.

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.

After using EXTINE

Storage

Keep EXTINE 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.

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

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

Do not store EXTINE or any other medicine in the bathroom or near a sink.

Do not leave EXTINE in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking EXTINE, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

EXTINE comes in 3 strengths of tablets:

- EXTINE 10 - oval yellow tablet marked "PX10" and ">".

- EXTINE 20 - oval white tablet marked "PX | 20" and ">".
- EXTINE 30 - oval blue tablet marked "PX30" and ">".

Each blister pack and bottle contains 30 tablets.

Ingredients

The active ingredient in EXTINE is paroxetine.

- each EXTINE 10 tablet contains 10 mg of paroxetine
- each EXTINE 20 tablet contains 20 mg of paroxetine
- each EXTINE 30 tablet contains 30 mg of paroxetine.

The tablets also contain:

- magnesium stearate
- sodium starch glycollate
- mannitol
- microcrystalline cellulose
- Eudragit E100
- Opadry Yellow AMB 80W12287 (10 mg only)
- Opadry White AMB OY-B-28920 (20 mg only)
- Opadry Blue AMB 80W90536 (30 mg only)

The tablets do not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer

Sigma Pharmaceuticals (Australia) Pty Ltd
(a member of the Sigma group of companies)
96 Merrindale Drive
Croydon Vic 3136
Tel: 03 - 9839 2800

Australian registration numbers:

Blister pack
EXTINE 10 - AUST R 120725
EXTINE 20 - AUST R 120729
EXTINE 30 - AUST R 120731
Bottle
EXTINE 10 - AUST R 120728
EXTINE 20 - AUST R 120730
EXTINE 30 - AUST R 120732

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