

Tipo di materiale	Descrizione	Destinazione	Lingua	Codice			
ISTRUZIONE	DROPAXIN 60 ml	 VENDITA	ingl. x LIBANO	PK11469	STYLEGRAPH		
Formato	N°. colori	Colore 1	Colore 2	Colore 3	Colore 4	TACCHE LAETUS	Corpo
500x150	1	P. 072 C					FRONTE 8
PELLICOLA DI PROPRIETÀ ITALFARMACO S.p.A.				VIETATA LA MANOMISSIONE - RENDERE DOPO LA STAMPA			

11-12-12

5. Stopping DROPAXIN

Do not stop taking DROPAXIN until your doctor tells you to. When stopping DROPAXIN, your doctor will help you to reduce your dose slowly over a number of weeks or months - this should help reduce the chance of withdrawal effects. One way of doing this is to gradually reduce the dose of DROPAXIN you take by 10 mg a week. Most people find that any symptoms on stopping DROPAXIN are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer. If you get withdrawal effects when you are coming off your drops your doctor may decide that you should come off them more slowly. If you get severe withdrawal effects when you stop taking DROPAXIN, please see your doctor. He or she may ask you to start taking your drops again and come off them more slowly. If you do get withdrawal effects, you will still be able to stop DROPAXIN.

Possible withdrawal effects when stopping treatment

Studies show that 3 in 10 patients notice one or more symptoms on stopping DROPAXIN. Some withdrawal effects on stopping occur more frequently than others. Likely to affect up to 1 in 10 people:

- Feeling dizzy, unsteady or off-balance
- Feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head
- Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take DROPAXIN
- Sleep disturbances (vivid dreams, nightmares, inability to sleep)
- Feeling anxious
- Headaches.

Likely to affect up to 1 in every 100 people:

- Feeling sick (nausea)
- Sweating (including night sweats)
- Feeling restless or agitated
- Tremor (shakiness)
- Feeling confused or disorientated
- Diarrhoea (loose stools)
- Feeling emotional or irritable
- Visual disturbances
- Fluttering or pounding heartbeat (palpitations).

Please see your doctor if you are worried about withdrawal effects when stopping DROPAXIN.

6. Children and adolescents under 18 years

DROPAXIN should not be used for children and adolescents under 18 years because it has not been proven to be an effective medicine for this age group. Also, patients under 18 have an increased risk of side-effects such as suicidal thoughts and harming themselves when they take DROPAXIN. If your doctor has prescribed DROPAXIN for you (or your child) and you want to discuss this, please go back to your doctor.

In studies of DROPAXIN in under 18s, common side effects that affected less than 1 in 10 children/adolescents were: an increase in suicidal thoughts and suicide attempts, deliberately harming themselves, being hostile, aggressive or unfriendly, lack of appetite, shaking, abnormal sweating, hyperactivity (having too much energy), agitation, changing emotions (including crying and changes in mood) and unusual bruising or bleeding (such as nose bleeds). These studies also showed that the same symptoms affected children and adolescents taking sugar pills (placebo) instead of DROPAXIN, although these were seen less often.

Some patients in these studies of under 18s had withdrawal effects similar to those seen in adults after stopping DROPAXIN (see Section 5. Stopping DROPAXIN, above). In addition, patients under 18 also commonly (affecting less than 1 in 10) experienced stomach ache, feeling nervous and changing emotions (including crying, changes in mood, trying to hurt themselves, thoughts of suicide and attempting suicide).

7. How to store DROPAXIN

- Keep your medicine out of the reach and sight of children.
- Do not use DROPAXIN after the expiry date which is stated on the carton after exp. The expiry date refers to the last day of that month.
- After first opening, the solution has a shelf life of 30 days for the bottle of 30 ml and 60 days for the bottle of 60 ml.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. What DROPAXIN contains

The active substance is paroxetine as the hydrochloride. The other ingredients are: Hydroxypropylbetadex, sucrose, aniseed flavoring agent (anethol, water, ethanol), sodium benzoate E211, purified water, hydrochloric acid 1 N.

What DROPAXIN looks like and contents of the pack

Each carton contains a bottle of 30 ml or 60 ml and a graduated pipette. Each ml of the liquid (20 drops) contains 10 mg of paroxetine.

Marketing Authorisation Holder

Italfarmaco S.p.A.
Via dei Lavoratori, 54
Cinisello Balsamo
Tel: +39.02.64431
Fax: +39.02.644346
e-mail: info@italfarmaco.com

Manufacturer

Italfarmaco S.A.,
28108 Alcobendas (Madrid) (E), San Rafael,
3 Polig. Industrial Alcobendas
Tel: +34.916572323
Fax: +34. 916572361
E-mail: info@italfarmaco.sp

This leaflet was last approved in

This medicinal product is authorised in the member states of the EEA under the following names:

Italy	DROPAXIN 10 mg/ml gocce orali, soluzione DROPAX 10 mg/ml – Tropfen zum Einnehmen, Lösung Prexat 10 mg/ml DROPAX 10 mg/ml belseöleges oldatos cseppek DROPAX 10 mg/ml, krople doustne, roztwór DROPAX 10 mg/ml gotas orais, solução Zuria 10 mg/ml gotas orales en solución
Austria	
Greece	
Hungary	
Poland	
Portugal	
Spain	

PK11469

PACKAGE LEAFLET: INFORMATION FOR THE USER

DROPAXIN 10 mg/ml oral drops, solution

Paroxetine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor.

- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What DROPAXIN is and what it is used for
2. Before you take DROPAXIN
3. How to take DROPAXIN
4. Possible side effects
5. Stopping DROPAXIN
6. Children and adolescents under 18 years
7. How to store DROPAXIN
8. What DROPAXIN contains

1. What DROPAXIN is and what it is used for

DROPAXIN is a treatment for adults with depression and/or anxiety disorders. DROPAXIN is one of a group of medicines called SSRIs (selective serotonin reuptake inhibitors).

Everyone has a substance called serotonin in their brain. People who are depressed or anxious have lower levels of serotonin than others. It is not fully understood how DROPAXIN and other SSRIs work but they

may help by increasing the level of serotonin in the brain.

Other medicines or psychotherapy can also treat depression and anxiety. Treating depression or anxiety disorders properly is important to help you get better. If it's not treated, your condition may not go away and may become more serious and more difficult to treat.

You may find it helpful to tell a friend or relative that you are depressed or suffering from an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

2. Before you take DROPAXIN

Do not take DROPAXIN

- If you have previously had an allergic reaction to paroxetine or any of the other liquid ingredients (listed below).
- If you are taking medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide), or have taken them at any time within the last two weeks. Your doctor will advise you how you should begin taking DROPAXIN once you have stopped taking the MAOI.
- If you are taking a tranquilliser called thioridazine.
- If you are taking an anti-psychotic called pimozide
- If you have previously had an allergic reaction to paroxetine or any of the other ingredients listed. See Section 8 What DROPAXIN contains, inside this leaflet.
- If any of these apply to you, tell your doctor without taking DROPAXIN.

Check with your doctor

- If you are taking any other medicines (see Other medicines and DROPAXIN, inside this leaflet);
- If you have eye, kidney, liver or heart

trouble;

- If you have epilepsy or have a history of fits;
- If you have episodes of mania (overactive behaviour or thoughts);
- If you are having electro-convulsive therapy (ECT)
- If you have a history of bleeding disorders;
- If you are taking tamoxifen to treat breast cancer or fertility problems, DROPAXIN may make tamoxifen less effective so your doctor may recommend you take another antidepressant;
- If you have diabetes;
- If you are on a low sodium diet;
- If you have glaucoma (elevated pressure in the eye)
- If you are pregnant or are planning to get pregnant (see Pregnancy and breast-feeding, inside this leaflet)

In these cases, and if you have not already discussed them with your doctor, go back to your doctor and ask what to do about taking DROPAXIN.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this: - If you have previously had thoughts about killing or harming yourself.

- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing

yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Pregnancy and breast-feeding

Talk to your doctor as soon as possible if you're pregnant, if you might be pregnant, or if you're planning to become pregnant. In babies whose mothers took DROPAXIN during the first few months of pregnancy, there have been some reports showing an increased risk of birth defects, in particular those affecting the heart. In the general population, about 1 in 100 babies are born with a heart defect. This increased to about 2 in 100 babies in mothers who took DROPAXIN. You and your doctor may decide that it is better for you to gradually stop taking DROPAXIN while you are pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking DROPAXIN.

Make sure your midwife or doctor knows you're taking DROPAXIN. When taken during pregnancy, particularly late pregnancy, medicines like DROPAXIN may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN). In PPHN, the blood pressure in the blood vessels between the baby's heart and the lungs is too high. If you take DROPAXIN during the last 3 months of pregnancy, your newborn baby might also have other conditions, which usually begin during the first 24 hours after birth. Symptoms include:

- trouble with breathing
- a blueish skin or being too hot or cold
- blue lips

Tipo di materiale	Descrizione	Destinazione	Lingua	Codice	
ISTRUZIONE	DROPAXIN 60 ml	 VENDITA	ingl. x LIBANO	PK11469	STYLEGRAPH

Formato	N°. colori	Colore 1	Colore 2	Colore 3	Colore 4	TACCHE LAETUS	Corpo
500x150	1	P. 072 C					RETRO 8

PELLICOLA DI PROPRIETÀ ITALFARMACO S.p.A.	VIETATA LA MANOMISSIONE - RENDERE DOPO LA STAMPA
--	--

11-12-12

- vomiting or not feeding properly
- being very tired, not able to sleep or crying a lot
- stiff or floppy muscles
- tremors, jitters or fits.

If your baby has any of these symptoms when it is born, or you are concerned about your baby's health, contact your doctor or midwife who will be able to advise you.

DROPAXIN may get into breast milk in very small amounts. If you are taking DROPAXIN, go back and talk to your doctor before you start breast-feeding. You and your doctor may decide that you can breast-feed while you are taking DROPAXIN. Medicines like DROPAXIN may reduce the quality of your sperm. Although the impact of this fertility is unknown, fertility may be affected in some men whilst taking DROPAXIN.

Other medicines and DROPAXIN

Some medicines can affect the way DROPAXIN works, or make it more likely that you'll have side effects. DROPAXIN can also affect the way some other medicines work. These include:

- Medicines called monoamine oxidase inhibitors (MAOIs, including moclobemide)- See Do not take DROPAXIN inside this leaflet
- Thioridazine or pimozide, which are anti-psychotics - See Do not take DROPAXIN inside this leaflet
- Aspirin, ibuprofen or other medicines called NSAIDs (non-steroidal anti-inflammatory drugs) like celecoxib, etodolac, meloxicam and refecoxib, used for pain and inflammation
- Tramadol or pethidine, painkillers
- Medicines called triptans, such as sumatriptan, used to treat migraine
- Other antidepressants including other SSRIs, tryptophan and tricyclic antidepressants like clomipramine,

- nortriptyline, desipramine
- Medicines such as lithium, risperidone, perphenazine, pimozide (called anti-psychotics or neuroleptics) used to treat some psychiatric conditions
- St John's Wort, a herbal remedy for depression
- Atomoxetine which is used to treat Attention Deficit Hyperactivity Disorder (ADHD)
- Phenobarbital, phenytoin or carbamazepine, used to treat fits or epilepsy
- Procyclidine, used to relieve tremor, especially in Parkinson's Disease
- Warfarin or other medicines (called anticoagulants) used to thin the blood
- Propafenone, flecainide and medicines used to treat an irregular heartbeat
- Metoprolol, a beta-blocker used to treat high blood pressure and heart problems
- Rifampicin, used to treat tuberculosis (TB) and leprosy
- Linezolid, an antibiotic
- Fentanyl, used in anaesthesia or to treat chronic pain
- A combination of fosamprenavir and ritonavir, which is used to treat Human Immunodeficiency Virus (HIV) infection
- Tamoxifen, which is used to treat breast cancer or fertility problems.

If you are taking any of the medicines in this list, and you have not already discussed these with your doctor, go back to your doctor and ask what to do. The dose may need to be changed or you may need to be given another medicine.

If you are taking any other medicines, including ones you have bought yourself, check with your doctor or pharmacist before taking DROPAXIN. They will know if it is safe for you to do so.

DROPAXIN and alcohol

Do not drink alcohol while you are taking

DROPAXIN. Alcohol may make your symptoms or side-effects worse.

Driving and using machinery

Possible side effects of DROPAXIN include dizziness, confusion, or changes in eyesight. If you do get these side effects, do not drive or use machinery.

Important information about some of the ingredients of DROPAXIN

This product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take it. The product contains 3,3% v/v of ethanol (in the aniseed flavouring agent). Therefore a 1 ml dose of DROPAXIN contains the equivalent to less than 1 ml of beer and 0,3 ml of wine (6 ml is equivalent to 4 ml of beer and 1.6 ml of wine). Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and patients with liver disease, or epilepsy. The product does not contain gluten and is suitable for patients affected by celiac disease.

Sportsmen and women

This medicine contains ethanol and can affect anti-doping tests.

3. How to take DROPAXIN

Take DROPAXIN drops, diluted in water, in the morning with food.

It is important to take your medicine as instructed by your doctor who will advise you what dose to take when you first start taking DROPAXIN. Most people start to feel better after a couple of weeks. If you don't start to feel better after this time, talk to your doctor, who may decide to increase the dose gradually, up to a

maximum daily dose.

The usual doses for different conditions are set out in the table below.

	Starting dose	Recommended daily dose	Maximum daily dose
Depression	2 ml	2 ml	5 ml
Obsessive Compulsive Disorder (obsessions and compulsions)	2 ml	4 ml	6 ml
Panic Disorder (panic attacks)	1 ml	4 ml	6 ml
Social Anxiety Disorder (fear or avoidance of social situations)	2 ml	2 ml	5 ml
Post Traumatic Stress Disorder	2 ml	2 ml	5 ml
Generalised Anxiety Disorder	2 ml	2 ml	5 ml

Your doctor will talk to you about the daily dose and how long to keep taking your medicine. This may be for many months or even longer.

Older people

The maximum dose for people over 65 is 4 ml per day.

Patients with liver or kidney disease

If you have severe liver or kidneys diseases, your doctor may decide that you should have a lower dose of DROPAXIN than usual.

If you forget to take DROPAXIN

Take your medicine at the same time every day. If you do forget a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose. You may possibly get withdrawal effects, but these should go away after you take your next dose at the usual time.

If you take more DROPAXIN than you should

If you or someone else take too much DROPAXIN drops, in addition to those symptoms mentioned under section 4 "Possible Side Effects", you could have vomiting, dilated pupils, fever, blood pressure changes, headache, involuntary muscle contractions, agitation, anxiety and faster than normal heartbeat.

In any case, tell your doctor or a hospital straight away. Show them the bottle of medicine.

What to do if you're feeling no better

DROPAXIN will not relieve your symptoms straight away- all antidepressants take time to work. Some people will start to feel better within a couple of weeks, but for others it may take a little longer. If you don't start to feel better after a couple of weeks, go back to your doctor who will advise you. Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started to feel better.

Possible side effects

As with other medicines DROPAXIN can cause side effects, but not everybody gets them. See the doctor if you get any of the following side effects during treatment. You may need to contact your doctor or go to a hospital straight away.

- Likely to affect up to 1 in every 100 people:
 - If you have unusual bruising or bleeding, including vomiting ,blood or passing blood in your stools, contact your doctor or go to a hospital straight away.
 - If you find that you are not able to pass water, contact your doctor or go to a hospital straight away.

- Likely to affect up to 1 in every 1,000 people:
 - If you experience seizures (fits), contact your doctor or go to a hospital straight away.

- If you feel restless and feel like you can't sit or stand still, you may have something called akathisia. Increasing your dose of DROPAXIN may make these feelings worse. If you feel like this, contact your doctor.
- If you feel tired, weak or confused and have achy, stiff or uncoordinated muscles this may be because your blood is low in sodium. If you have these symptoms, contact your doctor.

- Likely to affect up to 1 in every 10,000 people:
 - Allergic reactions to DROPAXIN. If you develop a red and lumpy skin rash, swelling of the eyelids, face, lips, mouth or tongue, start to itch or have difficulty breathing or swallowing, contact your doctor or go to a hospital straight away.

- If you have some or all of the following symptoms you may have something called serotonin syndrome. The symptoms include: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat. If you feel like this contact your doctor.

- Acute glaucoma. If your eyes become painful and you develop blurred vision, contact your doctor. Frequency unknown
- Some people have had thoughts of harming or killing themselves while taking DROPAXIN or soon after stopping treatment (see section 2, Before you take DROPAXIN).

Other possible side effects during treatment

- Likely to affect more than 1 in 10 people:
 - Feeling sick (nausea). Taking your medicine in the morning with food will reduce the chance of this happening.
 - Change in sex drive or sexual function. For example, lack of orgasm and, in men, abnormal erection and ejaculation.

- Likely to affect up to 1 in 10 people:
 - Increases in the level of cholesterol in the blood
 - Lack of appetite
 - Not sleeping well (insomnia) or feeling sleepy
 - Abnormal dreams (including nightmares)
 - Feeling dizzy or shaky (tremors)
 - Reduced mental concentration
 - Headache
 - Feeling agitated
 - Blurred vision
 - Yawning, dry mouth
 - Diarrhoea or constipation
 - Vomiting
 - Weight gain
 - Feeling weak
 - Sweating.

- Likely to affect up to 1 in every 100 people:
 - A brief increase in blood pressure, or a brief decrease that may make you feel dizzy or faint when you stand up suddenly
 - A faster than normal heartbeat
 - Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue

- Dilated pupils
- Skin rashes
- Feeling confused
- Having hallucinations (strange visions or sounds)
- An inability to urinate (urinary retention) or an uncontrollable, involuntary passing of urine (urinary incontinence).
- Likely to affect up to 1 in every 1,000 people:
 - Abnormal production of breast milk in men and women
 - A slow heartbeat
 - Effects on the liver showing up in blood tests of your liver function
 - Panic attacks
 - Overactive behaviour or thoughts (mania)
 - Feeling detached from yourself (depersonalisation)
 - Feeling anxious
 - Irresistible urge to move the legs (Restless Legs Syndrome)
 - Pain in the joints or muscles.

- Likely to affect up to 1 in every 10,000 people:
 - Liver problems that make the skin or whites of the eyes go yellow
 - Fluid or water retention which may cause swelling of the arms or legs
 - Sensitivity to sunlight
 - Severe cutaneous adverse reactions
 - Painful erection of the penis that won't go away
 - Unexpected bleeding, e.g. bleeding gums, blood in the urine or in vomit, or the appearance of unexpected bruises or broken blood vessels (broken veins)

- Some patients have developed buzzing, hissing, whistling, ringing or other persistent noise in the ears (tinnitus) when they take DROPAXIN. An increased risk of bone fractures has been observed in patients taking this type of medicines.
- If you have any concerns while you are taking DROPAXIN, talk to your doctor or pharmacist who will be able to advise you.