Citalopram 40 mg/ml oral drops, solution

Citalopram (as hydrochloride)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any of the side effects, talk to your doctor, pharmacist or nurse.

This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is, 'Citalopram 40 mg/ml oral drops, solution' will

What is in this leaflet:

1. What Citalopram oral drops are and what they are used for

be referred to as Citalopram oral drops throughout this leaflet.

- 2. What you need to know before you take Citalopram oral drops
- 3. How to take Citalopram oral drops
- 4. Possible side effects
- 5. How to store Citalopram oral drops
- 6. Contents of the pack and other information

1. WHAT CITALOPRAM ORAL DROPS ARE AND WHAT THEY ARE USED FOR

How does Citalopram oral drops work?

Citalopram is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants.

These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

What are Citalopram oral drops used for?

Citalopram oral drops contain citalopram and is used for the treatment of depression and, when you feel better, to help prevent these symptoms recurring. Citalopram is also used for long-term treatment to prevent the occurrence of new episodes of depression or if you have recurrent depression.

Citalopram is also beneficial in relieving symptoms if you tend to suffer from panic attacks.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CITALOPRAM ORAL DROPS

Do not take Citalopram oral drops:

- if you are allergic (hypersensitive) to citalopram, or any of the other ingredients of this medicine listed in section 6. Consult your doctor if you think you might be
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs). MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranyleypromine and moclobemide (used for the treatment of depression), selegiline (used in the treatment of Parkinson's disease) and linezolid (an antibiotic). Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranyleypromine you will need to wait 2 weeks before you start taking Citalopram oral drops. One day must elapse after you have finished taking moclobemide. After stopping Citalopram oral drops you must allow 1 week before taking any MAOI
- if you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm (see **Other medicines and Citalopram oral drops below**).

Warnings and precautions:

Talk to your doctor or pharmacist or nurse before taking Citalopram oral drops. Please tell your doctor if you have any medical problems, especially if you have:

- liver disease
- kidney disease
- diabetes (you may need an adjustment of your antidiabetic therapy)

• epilepsy or a history of seizures or fits

- History of a bleeding disorder or have ever suffered from bleeding in the stomach or intestine or if you are pregnant (see 'Pregnancy')
- mania or panic disorder
- low blood levels of sodium
- ECT (electroconvulsive therapy)
- ECT (electroconvulsive therapy)
- problems with your eyes, such as certain kinds of glaucoma
- a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)

• suffered or suffer from heart problems or have recently had a heart attack

• experienced a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.

Please consult your doctor, even if these statements were applicable to you at any time in the past

Please note: Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Medicines like Citalopram oral drops (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Special information relating to your disease

As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of Citalopram oral drops treatment it may take several weeks before you experience any improvement. In the beginning of the treatment certain patients may experience increased anxiety, which will disappear during continued treatment. Therefore, it is very important that you follow exactly your doctor's orders and do not stop the treatment or change the dose without consulting your doctor.

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
- 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.

Citalogram and drops should parmally not be used for shilds

Citalopram oral drops should normally not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Citalopram oral drops for patients aged under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram oral drops for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Citalopram oral drops. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram oral drops in this age group have not yet been demonstrated.

Other medicines and Citalopram oral drops

Medicines may affect the action of other medicines and this can sometimes cause serious adverse reactions.

Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Citalopram.

Tell your doctor or pharmacist if you are taking, have taken or might take any other medicines (including those purchased without prescription or any herbal medicines) during the last 14 days. This includes other medicines for depression (see **Do not take Citalopram oral drops** above).

- the herbal remedy St John's wort (*Hypericum perforatum*). This should not be taken at the same time as Citalopram oral drops
- monoamine oxidase inhibitors (MAOIs). These should not be taken at the same time as Citalopram oral drops (see **Do not take Citalopram oral drops** above).

Tell your doctor if you are taking, have recently taken or might take any other medicines.

- linezolid (an antibiotic)
- sumatriptan (used to treat migraine) or tramadol and comparable medicines (opioids, a pain killer). If you feel unwell when using these medicines with Citalopram oral drops you should see your doctor
- lithium (used to prevent and treat mania) and tryptophan (an anti-depressant)
 pimozida (a peuvolantia). This should not be taken at the same time as
- pimozide (a neuroleptic). This should not be taken at the same time as Citalopram oral drops
- imipramine and desipramine (used to treat depression)
- medicines containing selegiline (used to treat Parkinson's disease)
- cimetidine (used to treat stomach ulcers)
- mefloquine (used to treat malaria)
- bupropion (used to treat depression)
- medicines known to affect the blood platelets (e.g. anticoagulant drugs used to treat or prevent blood clots; aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and diclofenac used as painkillers; and some antipsychotic drugs and tricyclic antidepressants)
- metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure. The effects of either drug could be increased, decreased or altered
- neuroleptics (used in the treatment of schizophrenia).

Do not take Citalopram oral drops if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Citalopram oral drops with food and drink

Citalopram oral drops can be taken with or without food (see section 3 "How to take Citalopram oral drops").

As with all antidepressants, it is sensible to avoid drinking alcohol whilst receiving treatment although Citalopram oral drops has not been shown to increase the effects of alcohol.

Pregnancy

If you take Citalopram oral drops near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Citalopram oral drops so they can advise you.

Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, think you might be pregnant, or are planning to have a baby, tell your doctor. Do not take Citalopram oral drops if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

Make sure your midwife and/or doctor know you are on Citalopram oral drops. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram oral drops may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new-born (PPHN),

making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately. Also, if you take Citalopram oral drops during the last 3 months of your pregnancy and until the date of birth you should be aware that the following effects may be seen in your new-born: fits, being too hot or cold, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, overactive reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness or sleeping difficulties. If your new-born baby gets any of these symptoms please contact your midwife and/or doctor immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are breast-feeding, ask your doctor for advice. You should not breast-feed your baby when taking Citalopram oral drops because small amounts of the medicine can pass into the breast milk.

Fertility

Citalopram oral drops has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines

Citalopram oral drops does not usually affect the ability to carry out normal daily activities. However, if you feel dizzy or sleepy when you start to take this medicine, you should be careful when driving, operating machinery or performing jobs that need you to be alert until these effects wear off.

Citalopram oral drops contains ethanol (alcohol), E216 and E218

This medicine contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216), which may cause allergic reactions (possibly delayed). This medicine also contains small amounts of ethanol (alcohol), less than 100mg in all doses.

3. HOW TO TAKE CITALOPRAM ORAL DROPS

w much to take

Check with your doctor or pharmacist if you are not sure.

Adults

Always take this medicine exactly as your doctor or pharmacist has told you.

The usual dose is 16mg (8 drops) per day. This may be increased by your doctor

(8 drops) per day.

Depression

to a maximum of 32mg (16 drops) per day.

Panic disorder

The starting dose is 8mg (4 drops) per day for the first week before increasing the dose to between 16-24mg (8 to 12 drops) per day. The dose may be increased

by your doctor to a maximum of 32mg (16 drops) per day.

Elderly people (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 8-16mg per day. Elderly patients should not usually receive more than 16mg

Children and adolescents (less than 18 years of age)

Citalopram oral drops should not be given to children or adolescents under 18 years of age. For further information, see section 2, **What you need to know before you take Citalopram oral drops.**

Patients with special risks

Patients with liver complaints should not receive more than 16mg (8 drops) per day. If you have previously taken Citalopram tablets, you will find that the dose of your medicine in mg given as drops is a bit lower than that of tablets. This is because your body more easily absorbs the drops than the tablets, so you do not need as many mg to have the same effect.

The doses of tablets correspond to doses of drops as follows:

Tablets / dose Equivalent	Drops
10 mg	8 mg (4 drops)
20 mg	16 mg (8 drops)
30 mg	24 mg (12 drops)
40 mg	32 mg (16 drops)

Dimension: 450 x 310 mm Front Side

ARTWORK DETAIL LABEL

· · · · · · · · · · · · · · · · · · ·	TITLE BITCHE			
Citalopram 40mg/ml oral Solution- 15ml (BELTAPHARM)				
SPUK	Component	Pack Insert		
450 x 310 mm			Pack	
1048725	Old Item Code	1043248		
Black			No. of Colours	1
	Citalopram 40mg/ml oral Solution- 15ml SPUK 450 x 310 mm 1048725	SPUK Component 450 x 310 mm 1048725 Old Item Code	Citalopram 40mg/ml oral Solution- 15ml (BELTAPHARM) SPUK Component Pack Insert 450 x 310 mm Old Item Code 1043248	Citalopram 40mg/ml oral Solution- 15ml (BELTAPHARM) SPUK Component Pack Insert 450 x 310 mm Pack 1048725 Old Item Code 1043248

Change Control No.	PC-TSG/2023/062 - Record Number: 378039 Artwork Version 8				8.0	
Design/Style	Front & Back Printing. To be supplied in folded size 155 x 40mm-Brand name facing front side after final fold					
Substrate	40 GSM Paper.					
Special Instructions	Printing clarity to be clear & sharp.					
Autocartonator Requirements	NA					
Prepared By:		Rewiewed By:	Approved By:	Approved By:	Authorised	d By:
PDC - AW		PDC - Tech	Mkt/BD	RAD	QA	
		FOI	R ARTWORK REVISION PUR	RPOSE		
To be filled by SCM (Planning) Eff		Effective Date:		Sign & Date:		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT**

MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.

RD/PD/003/F-01/R0

How and when to take Citalopram oral drops

The drops are for oral use and can be taken in a drink of water, or orange or apple juice.

Citalopram oral drops is taken every day as one dose at any time of the day.

Like other medicines for depression and panic disorder these drops may take a few weeks before you feel any improvement. Continue to take Citalopram oral drops even if it takes some time before you feel any improvement in your

The duration of treatment is individual, usually at least 6 months. Continue to take the drops for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

Patients who have recurrent depression benefit from continued treatment, sometimes for several years, to prevent the occurrence of new depressive episodes.

Never change the dose of the medicine without talking to your doctor first.

If you think that you or anyone else may have taken too many Citalopram

If you take more Citalopram oral drops than you should

oral drops, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the Citalopram oral drops box/container with you if you go to a doctor or hospital so that the doctor knows what you have taken. Some of the signs of an overdosage could be life-threatening.

Symptoms of overdosage may include:

- irregular heart beat
- seizures
- changes in heart rhythm
- feeling sick (nausea)
- vomiting
- sweating
- drowsiness
- unconsciousness
- fast heart beats
- tremoi
- changes in blood pressure
- serotonin syndrome (see section 4)
- agitation dizziness
- enlarged eye pupils
- bluish skin
- · breathing too quickly.

If you forget to take Citalopram oral drops

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose.

If you stop taking Citalopram oral drops

Stopping this medicine quickly may cause symptoms such as dizziness, nausea and numbness or tingling in hands or feet, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling or being sick, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). These are usually non-serious and disappear within a few days. When you have completed your course of treatment, the dose of Citalopram oral drops is usually reduced gradually over a couple of weeks.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Several of the effects listed below can also be symptoms of your illness and may disappear as you start to get better.

Serious side effects

Stop taking Citalopram oral drops and seek medical advice immediately if you have any of the following symptoms:

- difficulty in breathing
- swelling of the face, lips, tongue or throat that causes difficulty in swallowing or breathing
- severe itching of the skin (with raised lumps) • fast, irregular heartbeat, fainting which could be symptoms of a life-

If you notice any of the following you should contact your doctor immediately

as your dose may need to be reduced or stopped:

threatening condition known as torsades de pointes.

- you start having fits for the first time or fits that you have suffered from in
- the past before become more frequent
- your behaviour changes because you feel elated or over excited
- you experience high fever, agitation, confusion, and trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome
- tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium (hyponatraemia).

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

The following side effects are often mild and usually disappear after a few days'

- **Very common** (may affect more than 1 in 10 people)
- sleepiness
- · difficulty in sleeping
- · increased sweating
- dry mouth (a dry mouth increases the risk of tooth decay, so be sure to clean your teeth more often than usual)
- feeling sick (nausea)
- headache
- changes in your sleeping pattern
- loss of body strength, weakness.

Common (may affect up to 1 in 10 people)

- lack of appetite
- agitation
- · decreased sex drive anxiety
- nervousness
- confusion · abnormal dreams
- tremor
- reduced emotions, indifference (apathy)
- tingling or numbness in the hands or feet
- dizziness
- problems concentrating
- ringing in the ears (tinnitus) migraine
- loss of memory (amnesia)
- pounding heartbeat (palpitations) yawning
- blocked or runny nose (rhinitis)
- diarrhoea
- vomiting
- · constipation
- stomach pain
- flatulence (wind)
- increase in saliva (drooling)
- itching
- pain in muscles and joints • for men, problems with ejaculation and erection
- for females, failing to reach an orgasm
- · prickling of the skin · loss of weight.

- **Uncommon** (may affect up to 1 in 100 people)
- · bruising easily
- · increased appetite
- · aggression
- hallucinations
- · mania

· fainting

- large pupils (the dark centre of the eye)
- · fast heart beat
- slow heart beat
- · nettle rash
- · loss of hair

rash

- sensitivity to sunlight
- · difficulties urinating
- excessive menstrual bleeding • swelling of the arms or legs
- · increased weight
- · episodes of feeling disconnected from one's body and thoughts (depersonalization).

Rare (may affect up to 1 in 1000 people)

- increased sex drive
- · convulsions
- involuntary movements taste disturbances
- bleeding
- · coughing
- hepatitis
- feeling unwell (malaise)
- · fever.

Not known (frequency cannot be estimated from the available data)

- Increase in a hormone called prolactin in the blood
- an increase in bleeding or bruising caused by a decrease in blood platelets (thrombocytopenia)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see (see 'Pregnancy') in section 2 for more information
- rash (hypersensitivity)
- low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythms
- · panic attack
- grinding teeth
- restlessness
- · unusual muscle movements or stiffness • involuntary movements of the muscles (akathisia)
- low blood pressure
- bleeding disorders including skin and mucosal bleeding (ecchymosis)
- sudden swelling of skin or mucosa · in men, painful erections
- flow of breast milk in men or in women who are not breast-feeding (galactorrhoea)
- · abnormal liver function tests • an increased risk of bone fractures has been observed in patients taking this
- type of medicines • trouble in seeing (vision disturbance)

· excessive uterine bleeding (metrorrhagia). SSRIs can, very rarely, increase the risk of bleeding, including stomach or intestinal bleeding. Let your doctor know if you vomit blood or develop black or blood stained stools.

Also let your doctor know if you continue to have other symptoms associated with your depression. This might include hallucinations, anxiety, mania or confusion.

Any side effects that do occur will usually disappear after a few days. If they are troublesome or persistent, or if you develop any other unusual side effects while taking Citalopram oral drops, please tell your doctor.

If you experience any other side effects not mentioned in this leaflet please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CITALOPRAM ORAL DROPS

- · Keep this medicine out of the sight and reach of children.
- After breaking the seal for the first time, the drops can be used for 16 weeks if stored below 25°C (room temperature).
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Citalopram oral drops contains

The active substance in Citalopram oral drops is citalopram (as hydrochloride). Each 1ml of Citalopram oral drops contains 40mg of citalopram (as hydrochloride). Each 1ml of Citalopram oral drops, solution contains 20 drops. Each drop contains 2mg citalopram (as hydrochloride).

The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), purified water, ethanol and hydroxyethylcellulose.

What Citalopram oral drops looks like and contents of the pack

Citalopram oral drops is a clear, colourless to pale yellowish liquid supplied in an amber coloured glass bottle.

Marketing Authorisation Holder

Strides Pharma UK Ltd. Unit 4, The Metro Centre, Dwight Road, Watford, WD18 9SS

United Kingdom Manufacturer Beltapharm S.P.A

Italy

Via Stelvio, 66 20095 Cusano Milanino (MI)

This leaflet was last revised in 08/2023.



Dimension: 450 x 310 mm

Back Side

ADTWODE DETAIL LADEL

ARTWORK DETAIL LABEL					
Product Citalopram 40mg/ml oral Solution- 15ml (BELTAPHARM)					
Buyer/Country	SPUK	Component	Pack Insert		
Dimension	450 x 310 mm			Pack	
New Item Code	1048725	Old Item Code	1043248		
Colour Shades	Black			No. of Colours	1

Design/Style	Front & Back Printing. To be supplied in folded size 155 x 40mm-Brand name facing front si
Substrate	40 GSM Paper.
Special Instructions	Printing clarity to be clear & sharp.
Autocartonator	A1A

Change Control No. PC-TSG/2023/062 - Record Number: 378039

MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.

Prepared By: Rewiewed By: Approved By: Approved By: Authorised By: PDC - AW PDC - Tech Mkt/BD QA

To be filled by SCM (Planning) | Effective Date: Sign & Date:

provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT

RD/PD/003/F-01/R0

Artwork Version 8.0

side after final fold

Changes done on: 20.03.2023

Requirements