

PACKAGE LEAFLET: INFORMATION FOR THE USER
Fluoxetine 60 mg Hard Capsules
Fluoxetine

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 signs of illness are the same as yours.

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fluoxetine 60 mg Hard Capsules are and what they are used for
2. What you need to know before you take Fluoxetine 60 mg Hard Capsules
3. How to take Fluoxetine 60 mg Hard Capsules
4. Possible side effects
5. How to store Fluoxetine 60 mg Hard Capsules
6. Contents of the pack and other information

1. What Fluoxetine 60 mg Hard Capsules are and what they are used for

Fluoxetine is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants.

Fluoxetine 60 mg Hard Capsules are used to treat adults with:

- Major depressive episodes
- Bulimia nervosa: Fluoxetine 60 mg Hard Capsules are used alongside psychotherapy for the reduction of binge-eating and purging.
- Obsessive compulsive disorder (also called OCD).

2. What you need to know before you take Fluoxetine 60 mg Hard Capsules

Do not take Fluoxetine 60 mg Hard Capsules and tell your doctor or pharmacist if the following apply:

- If you are allergic (hypersensitive) to fluoxetine or any of the other ingredients of Fluoxetine 60 mg Hard Capsules (listed in Section 6). An allergy may include rash; itching, swollen face or lips or shortness of breath.
- If you are taking metoprolol for treating cardiac failure
- If you are taking medicines known as irreversible non-selective monoamine oxidase inhibitors (also called MAOIs) (which are also used to treat depression), since serious or even fatal reactions can occur.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluoxetine 60 mg Hard Capsules if any of the following applies to you:

- If you develop a rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the capsules straight away and contact your doctor immediately.
- If you have epilepsy or have had a fit in the past; if you have a fit (seizure) or experience an increase in seizure frequency, contact your doctor immediately, the use of fluoxetine might need to be discontinued.
- If you are having Electroconvulsive therapy (ECT)
- If you have suffered from abnormally elevated mood (mania) in the past, if you have an episode of abnormally elevated mood, contact your doctor immediately, the use of fluoxetine might need to be discontinued.
- If you have any liver or kidney problems, you should discuss this with your doctor, as he may wish to reduce the dose.
- If you are taking tamoxifen (for treatment of breast cancer (see 'Other medicines and Fluoxetine 60 mg Hard Capsules'))
- If you suffer from congenital heart defect (congenital long QT syndrome) or someone in your family shows variations in the electrical activity of the heart or you tend to show irregular heartbeat (e.g. because of low levels of potassium, low levels of magnesium, slow heartbeat, heart attack or uncompensated heart failure).
- If you have diabetes. You may need to adjust your dose of insulin or other antidiabetic treatment.
- If you have a history of bleeding disorders or you develop bruises or unusual bleeding or if you are pregnant (see 'Pregnancy')
- If you are using medicinal products that affect the coagulation of blood (see 'Other medicines and Fluoxetine 60 mg Hard Capsules')
- If you have raised intraocular pressure or are at risk of acute narrow-angle glaucoma.
- If you start to experience fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation; you may suffer from the so called serotonin syndrome or neuroleptic malignant syndrome. Although this syndrome occurs rarely it may result in potentially life threatening conditions, contact your doctor immediately, the use of fluoxetine might need to be discontinued.
- The use of Bupropione together with Fluoxetine capsules can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Fluoxetine 60 mg Hard Capsules').

Irreversible non-selective MAOI: Treatment with fluoxetine should only be started 2 weeks after discontinuation of an irreversible non-selective MAOI. Do not take any MAOIs for at least five weeks after you stop taking Fluoxetine 60 mg Hard Capsules. Examples of irreversible non-selective MAOIs include nialamide, iproniazide, moclobemide, phenelzine, tranylcypromine and isocarboxazid.

Reversible MAOI: It is not recommended to combine fluoxetine with a reversible MAOI (e.g. moclobemide). Treatment with fluoxetine can be started the following day after ending of a reversible MAOI.

Suicidal thoughts and worsening of your depression/anxiety disorder

If you are depressed or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when 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.

Akathisia/inner restlessness: The use of fluoxetine has been associated with the development of akathisia, characterised by a subjectively unpleasant or distressing restlessness and need to move often accompanied by an inability to sit or stand still. This is most likely to occur within the first few weeks of treatment. In patients who develop these symptoms, increasing the dose may be detrimental.

Sexual dysfunction: Medicines like Fluoxetine 60 mg Hard Capsules (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Withdrawal symptoms seen on discontinuation of SSRI treatment: Withdrawal symptoms are common when treatment is discontinued, particularly if discontinuation is abrupt (see How to take Fluoxetine 60 mg Hard Capsules).

The risk of withdrawal symptoms may be dependent on several factors, including the length of treatment, the prescribed dose and how quickly the dose is reduced. Effects that may be noticed when stopping treatment are listed in Section 3 under 'If you stop taking Fluoxetine 60 mg Hard Capsules'. Generally, these symptoms are mild to moderate; however, sometimes they may be more intense. They usually occur within the first few days of stopping treatment and usually disappear within 2 weeks, but in some people they may last for 2-3 months or more. Therefore fluoxetine should be gradually decreased when stopping treatment over a period of at least one to two weeks (see 'How to take Fluoxetine 60 mg Hard Capsules').

Other medicines and Fluoxetine 60 mg Hard Capsules

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, (up to five weeks ago) including medicines obtained without prescription. This medicine may affect the way some other medicines work (interaction).

- buprenorphine/opioids. These medicines may interact with Fluoxetine capsules and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

You must not take fluoxetine together with

- Irreversible, non-selective MAO-inhibitors (e.g. iproniazid; used to treat depression). These must not be used with Fluoxetine 60 mg Hard Capsules as serious or even fatal reactions (serotonin syndrome) can occur (see section 'Do not take Fluoxetine 60 mg Hard Capsules'). MAO inhibitors type B (selegiline) can be used with Fluoxetine 60 mg Hard Capsules provided that your doctor monitors you closely.
- Metoprolol (used to treat cardiac failure): Since fluoxetine may slow down metabolism of metoprolol and increase the risk of side effects of metoprolol including pronounced slowing of the heartbeat.

Not recommended is a combination of fluoxetine with

- Tamoxifen (used to treat breast cancer): Since fluoxetine may influence blood levels of tamoxifen and lower its efficacy.
- MAO inhibitors type A (linezolid, methylnihonium chloride (methylene blue) as the risk of developing a serotonin syndrome arises. When fluoxetine is used in combination with one of these drugs your doctor will carry out more frequent check-ups.
- Reversible MAOI: It is not recommended to combine fluoxetine with a reversible MAOI (e.g. moclobemide). Treatment with fluoxetine can be started the following day after ending of a reversible MAOI.
- Mequitazine: Since fluoxetine may influence blood levels of mequitazine and increase the risk of side effects (QT prolongation).

Combinations requiring caution:

- Phenytoin (for epilepsy); because Fluoxetine 60 mg Hard Capsules may influence the blood levels of this drug, your doctor may need to introduce phenytoin more carefully and carry out check-ups when given with Fluoxetine 60 mg Hard Capsules.
- Lithium (used to treat depression), tramadol (painkiller), triptans (used to treat migraine), tryptophan, selegiline (MAO inhibitors type B), St. John's Wort (*Hypericum perforatum*): There is an increased risk of serotonin syndrome when these drugs are coadministered with Fluoxetine 60 mg Hard Capsules. When fluoxetine is used in combination with one of these drugs your doctor will carry out more frequent check-ups.
- Drugs that may have an effect on heart rhythm such as Class IA and III antiarrhythmics, anti-psychotics (e.g. phenothiazine derivatives, pimozide, haloperidol); tricyclic antidepressants, certain antimicrobial agents (e.g. sparfoxacin, moxifloxacin, erythromycin IV, pentamidine), anti-malaria treatment particularly halofantrine, certain antihistamines (astemizole, mizolastine)
- Warfarin, non-steroidal anti-inflammatory drugs or other medicines used to thin the blood (including clozapine, used to treat certain mental disorders, and acetylsalicylic acid (AS); Fluoxetine 60 mg Hard Capsules may alter the effect of these medicines on the blood. If Fluoxetine 60 mg Hard Capsules treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests.
- Cyproheptadine: Cyproheptadine may reduce antidepressant effect of fluoxetine.
- Drugs that may lower sodium concentration in the blood (e.g. diuretics, carbamazepine, oxcarbazepine)
- Combination with agents that may lower the seizure threshold (e.g. tricyclic antidepressants, other selective serotonin reuptake inhibitors: phenothiazine, mefloquine, chloroquine, bupropion, tramadol)
- Electroconvulsive therapy (ECT): There are rare cases of prolonged seizures in patients that have received an ECT while taking fluoxetine.
- Flecainide, propafenone and nebivolol (used to treat heart diseases)
- carbamazepine (used to treat epilepsy), tricyclic antidepressants (imipramine, desipramine, amitriptyline), Risperidon (neuroleptic), atomoxetine: As Fluoxetine 60 mg Hard Capsules may possibly change the blood levels of these drugs, your doctor may need to lower their dose when administered with Fluoxetine 60 mg Hard Capsules. This also applies if you have been treated with fluoxetine in the last five weeks.

Taking Fluoxetine 60 mg Hard Capsules with food and drink

You should avoid alcohol while you are taking this medicine. You can take your capsules with or separately from food.

Children and adolescents

Fluoxetine 60 mg Hard Capsules should not be used in children and adolescents under the age of 18. Lower strength fluoxetine medicine in a liquid or capsule form is available that is better suited to patients of this age group.

Pregnancy, breast-feeding and fertility

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

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. Make sure your midwife and/or doctor know you are on Fluoxetine.

Pregnancy

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.

If you take Fluoxetine 60 mg Hard Capsules 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 Fluoxetine 60 mg Hard Capsules so they can advise you.

Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor, muscle weakness, persistent crying, difficulty in sucking or in sleeping.

In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some reports suggesting an increased risk of birth defects 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 fluoxetine.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Fluoxetine 60 mg Hard Capsules may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (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.

It is preferable not to use this treatment during pregnancy unless the potential benefit outweighs the potential risk. Thus, you and your doctor may decide that it is better for you to gradually stop taking fluoxetine while you are pregnant or before being pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking fluoxetine.

Breast-feeding

Fluoxetine is excreted in breast milk and can cause side effects in babies. You should only breast-feed if it is clearly necessary. If breastfeeding is continued, your doctor may prescribe a lower dose of fluoxetine.

Fertility

Fluoxetine 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 machinery

Some medicines may affect your judgement or co-ordination. Do not drive or use machinery unless you are sure that you are not affected.

Fluoxetine 60 mg Hard Capsules contain Tarrazine (E102) and Sunset Yellow FCF (E110)

These ingredients may cause allergic reactions in some people.

3. How to take Fluoxetine 60 mg Hard Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Fluoxetine 60 mg Hard Capsules are for use by adults for depression, bulimia nervosa, obsessive compulsive disorder (OCD).

Your doctor will tell you how many capsules to take, and when to take them.

You can take your capsules with or separately from food.

The capsules should not be chewed or crushed; they should always be swallowed whole, with a drink of water.

Dosage information

Your doctor may start you on lower strength fluoxetine (e.g. 20 mg) capsules that are available, but check with your doctor or pharmacist if you are not sure of the correct dose.

• **Depression:** The recommended dose is 20 mg daily. Your doctor will review and adjust your dosage if necessary within 3 to 4 weeks of the start of treatment. When appropriate the dosage can be gradually increased up to a maximum of 60 mg. The dose should be increased carefully to ensure that you receive the lowest effective dose. You may not feel better immediately when you first start taking your medicine for depression. This is usual because an improvement in depressive symptoms may not occur until after the first few weeks. Patients with depression should be treated for a period of at least 6 months.

• **Bulimia nervosa:** The recommended dose is 60 mg daily.

• **OCD:** The recommended dose is 20 mg daily. Your doctor will review and adjust your dosage if necessary after 2 weeks of treatment. When appropriate the dosage can be gradually increased up to a maximum of 60 mg. If no improvement is noted within 10 weeks, treatment with fluoxetine should be reconsidered.

Elderly:

If you are elderly, your doctor will increase the dose with more caution and the daily dose should generally not exceed 40 mg. The maximum dose is 60 mg per day.

Liver impairment:

If you have a liver problem or are using other medication that might have an influence on fluoxetine, your doctor may decide to prescribe a lower dose or instruct you to use fluoxetine every other day.

Fluoxetine 60 mg Hard Capsules should not be used in children and adolescents under the age of 18.

If you take more Fluoxetine 60 mg Hard Capsules than you should

If you take too many capsules, go to your nearest hospital emergency department (or casualty) or tell your doctor straight away. Take the pack of Fluoxetine 60 mg Hard Capsules with you if you can. Symptoms of overdose include: nausea, vomiting, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental condition ranging from agitation to coma.

If you forget to take Fluoxetine 60 mg Hard Capsules

If you forget to take your dose, do not worry. Take your next dose the next day at the usual time. Do not take a double dose to make up for a forgotten individual dose. Taking your medicine at the same time each day may help you to remember to take it regularly.

If you stop taking Fluoxetine 60 mg Hard Capsules

Always follow your doctor's instructions on how many Fluoxetine 60 mg Hard Capsules to take and for how long to take them. Keep taking your medicine until your doctor asks you to stop. Do not stop taking your medicine without asking your doctor first, even when you start to feel better. Make sure you do not run out of capsules.

When your doctor does instruct you to stop taking Fluoxetine 60 mg Hard Capsules he/she will help you to reduce your dose slowly over one to two weeks – this should help reduce the chance of withdrawal effects.

You may notice the following effects when you stop taking Fluoxetine 60 mg Hard Capsules: dizziness; tingling feelings like pins and needles; sleep disturbances (vivid dreams, nightmares, inability to sleep); feeling restless or agitated; unusual tiredness or weakness; feeling anxious; nausea/vomiting (feeling sick/being sick); tremor (shakiness); headaches.

Most people find that any symptoms on stopping Fluoxetine 60 mg Hard Capsules (under guidance from your doctor) are mild and go away on their own within a few weeks. If you experience symptoms when you stop treatment, contact your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if:

- You have distressing thoughts, thoughts of harming yourself or committing suicide
- You get a rash or an allergic reaction such as itching, swollen lips, tongue or face, wheezing or shortness of breath. If this happens, stop taking the capsules straight away and tell your doctor immediately.
- You feel restless and feel like you cannot sit or stand still. You may have something called *akathisia*; increasing your dose of Fluoxetine 60 mg Hard Capsules may make you feel worse. If you feel like this, contact your doctor.
- Your skin starts to turn red or you develop a varied skin reaction or your skin starts to blister or peel. This is very rare.
- A combination of symptoms (known as Serotonin Syndrome), including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or tremor, confusion, extreme agitation or sleepiness (only rarely).
- Feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people on diuretics (water tablets)
- Prolonged and painful erection
- Irritability and extreme agitation
- Heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate.
- Inexplicable vaginal bleeding
- Inexplicable bruises or bleeding or bleeding in the gastrointestinal tract
- Fits
- Uncontrollable movements
- Signs of liver inflammation (abdominal swelling, distention or bloating, diarrhoea, discoloured urine and stool, fatigue, headache, itchy skin, joint pain, loss of appetite, low-grade fever, malaise and lethargy, nausea with or without vomiting, yellowing of the skin and whites of the eye)
- Small bleedings of skin and mucosa, painless (rarely itching) skin swelling, acute, inflammatory skin disease, heavy skin reactions, Stevens-Johnson syndrome, Erythema multiforme, Toxic Epidermal Necrolysis (Lyell Syndrome)

The following side effects have been reported in patients during treatment with fluoxetine:

Very common (may affect more than 1 in 10 people):

- Inability to sleep
- Headache
- Diarrhoea
- Sickness
- Tiredness

Common (may affect up to 1 in 10 people):

- Poor appetite
- Change in taste
- Nervousness, anxiety
- Feeling tense
- Decreased sex drive or sexual difficulties (including low sexual performance and ejaculation problems)
- Sleep problems or unusual dreams
- Tremor
- Not being able to concentrate or think properly
- Drowsiness
- Blurred vision
- Flushing
- Yawning
- Indigestion, vomiting
- Dry mouth
- Skin rash, urticaria, itching, abnormal sweating
- Joint pains
- Passing urine too frequently
- Feeling shaky or chills
- Weight loss

Uncommon (may affect up to 1 in 100 people)

- Feeling detached from yourself
- Abnormal thinking
- Abnormally high mood
- Orgasm problems
- Teeth grinding
- Disturbances of motion sequence
- Disturbances of coordination
- Muscle twitching

- Involuntary impaired balance
- Memory impairment
- Enlarged pupils
- Ringing in the ears
- Low blood pressure
- Shortness of breath
- Nose bleeds
- Difficulties in swallowing
- Hair loss
- Inexplicable bruises or bleedings, also in gastrointestinal tract
- Cold sweat
- Difficulty passing urine
- Sexual disorders
- Sensation disorders, discomfort
- Feeling hot or cold

- Rare (may affect up to 1 in 1,000 people)
- Low levels of sodium in the blood
 - Low numbers of platelets
 - Low number of red and white blood cells
 - Manic reactions (untypical wild behaviour)
 - Hallucinations
 - Upmanship, aggression
 - Panic attacks
 - Confusion
 - Sluttering
 - Fits
 - Agitation
 - Uncontrollable movements
 - Buccoglossal Syndrome
 - Arrhythmias and QT prolongation
 - Inflammation of blood vessels and vascular dilation
 - Pharyngitis
 - Oesophageal pain
 - Liver inflammation
 - Lung problems
 - Sensitivity to sun light
 - Muscle aches
 - Difficulties in passing urine
 - Producing breast milk
 - Anaphylactic reaction (shortness of breath, swelling in the throat, low blood pressure, gastrointestinal complaints, racing heart, vertigo, shock)
 - Serum sickness (rash, joint aches, fever, swelling of lymph nodes, shock, low blood pressure)
 - Impaired ADH secretion
 - Increased prolactin levels in the blood
 - Abnormal liver function tests

Frequency not known:

- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy in section 2 for more information

Most of these are usually nothing to worry about and go away after the first few weeks while you are taking your medicine.

If any of the side effects get serious or you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Children and Adolescents (8-18 years) if treated with lower doses for moderate or severe depressive episodes may experience slow growth or delayed sexual maturity and have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger).

Do not stop taking Fluoxetine 60 mg Hard Capsules until your doctor tells you to.

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 Website: 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 Fluoxetine 60 mg Hard Capsules

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage conditions. Do not use Fluoxetine 60 mg Hard Capsules after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month. 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 Fluoxetine 60 mg Hard Capsules contain

- The active substance is fluoxetine hydrochloride.
- The other ingredients are pregelatinised (maize) starch, gelatin capsules (containing tartrazine (E102) [0.37mg], sunset yellow FCF (E110) [0.0009mg], titanium dioxide (E171), sodium lauryl sulphate, sorbitan monolaurate and gelatin) and black printing ink consisting of black iron oxide (E172), propylene glycol and shellac.

What Fluoxetine 60 mg Hard Capsules look like and contents of the pack

Fluoxetine 60 mg Hard Capsules are yellow and white capsules, marked 'FLX 60'.

Your Fluoxetine 60 mg Hard Capsules are presented in blister packs. They are supplied in boxes containing 5, 7, 10, 14, 28, 30, 42, 56 or 60 capsules. Not all pack sizes may be marketed.

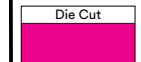
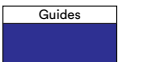
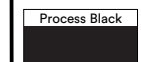

Marketing Authorisation Holder and Manufacturer:

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Fluoxetine 60 mg Hard Capsules/
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Artwork	
Brand:	Dr Reddy's
Product Name:	Fluoxetine
Strength:	60 mg
Form:	Capsules
Component:	Leaflet
Pack Size:	30 Capsules
Country:	UK
Date Created:	25 Mar 2020
Date Modified:	19 NOV 2021
Version:	1.3
Technical Information	
Die Cut	Guides
	
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