

PACKAGE LEAFLET

Package leaflet: Information for the user

Flexilev 5 mg/1.25 mg dispersible tablets for dose dispenser

levodopa/carbidopa

Read all of this leaflet carefully before you start using 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 Flexilev is and what it is used for
2. What you need to know before you take Flexilev
3. How to take Flexilev
4. Possible side effects
5. How to store Flexilev
6. Contents of the pack and other information

1. What Flexilev is and what it is used for

Flexilev improves the signs of Parkinson's disease. Parkinson's disease is a long-term illness where:

- you become slow and unsteady
- your muscles feel stiff
- you may develop shaking or trembling (called 'tremor').

If not treated, Parkinson's disease can make it hard for you to continue your normal daily activities.

Flexilev contains two different medicines called levodopa and carbidopa.

- levodopa turns into a material called 'dopamine' in your brain. The dopamine helps to improve the signs of your Parkinson's disease.
- carbidopa belongs to a group of medicines called 'aromatic amino acid decarboxylase inhibitors'. It helps levodopa work more effectively by slowing the speed at which levodopa is broken down in your body.

Flexilev are small "minitablets" which are taken using a separately provided dose dispenser called MyFID. The dose dispenser which can be programmed by your doctor or nurse delivers a certain number of tablets for each scheduled dose.

2. What you need to know before you take Flexilev

Do not take Flexilev:

- if you are allergic to carbidopa or levodopa or any of the other ingredients of this medicine (listed in section 6).
- if you are taking certain medicines called 'MAOIs' (Monoamine Oxidase Inhibitors) used for depression. You need to stop using these medicines at least two weeks before you start Flexilev (see also under 'Taking other medicines' below).

- if you have a condition called ‘narrow-angle glaucoma’ that may cause a sudden build up of pressure in the eye
- if you suffer from attacks of hypertension induced by tumor of the adrenal medulla (pheochromocytoma)
- hormonal problems (overproduction of cortisol or thyroid hormone)
- if you suffer from psychosis

Do not take Flexilev if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Flexilev.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flexilev:

- if you have a history of fits (convulsions)
- if you have a lung problem (such as bronchial asthma)
- if you have had an ulcer in your gut (called ‘duodenal’ or ‘peptic ulcer’) or have vomited blood
- if you have had a heart attack or heartbeat problems
- if you are taking a medicine which may cause low blood pressure when rising from a chair or bed (orthostatic hypotension)
- if you have kidney or liver problems
- if you have hormonal problems
- if you have had or have depression or other mental problems
- if you sometimes have sudden sleep attacks or sometimes feel very sleepy
- if you are due to have surgery.
- if you have ever had skin cancer or you have any unusual moles which have not been examined by your doctor

Tell the doctor if you or your family/carer notices you are developing urges or cravings to behave in ways that are unusual for you or you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These behaviours are called impulse control disorders and can include addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to review your treatments.

Tell your doctor if you or your family/carer notices you are developing addiction-like symptoms leading to craving for large doses of Flexilev and other medicines used to treat Parkinson’s disease.

This medication can affect some laboratory tests that your doctor may perform on blood or urine samples. If you are unsure if any of the above applies to you, talk to your doctor or pharmacist.

Other medicines and Flexilev

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and over the counter medicines. The effect of the treatment may be affected if Flexilev and certain other drugs are taken concomitantly.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Tolcapone, entacapone, amantadine (against Parkinson’s disease)
- Anticholinergics and sympathomimetics (against severe allergic reactions, asthma, chronic bronchitis, heart diseases and low blood pressure)
- Phenytoin (against convulsions or epilepsy)
- Antihypertensives (against high blood pressure)
- Antipsychotics such as phenothiazines, butyrophenones and risperidone (against mental problems)
- Tricyclic antidepressants or non-selective monoamine oxidase inhibitors (against depression)
- Isoniazide (against tuberculosis)
- Benzodiazepines (against anxiety)
- Iron tablets (against anaemia)
- Metoclopramide (against sickness)

- Papaverine (against spasms in the blood vessels)
- Catechol-O-methyltransferase inhibitor (for the treatment of Parkinson's disease)
- Tetrabenazin (against excessive, involuntary movements)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is limited experience with the use of Flexilev during pregnancy.
It is unknown whether Flexilev passes into breast milk.

Driving and using machines

- Flexilev affects different people in different ways. Flexilev may lower your blood pressure, which may make you feel light-headed or dizzy. Therefore, be particularly careful when you drive or when you use any tools or machines. (see '**Possible side effects**').

Flexilev can also make you sleepy or cause 'sudden sleep attacks'. If this happens to you, you must not drive or use tools or machines, until the attacks or drowsiness have ceased.

3. How to take Flexilev

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dosage will be decided by your doctor.

Your doctor will monitor you on a regular basis and adjust your dosage if necessary.

The tablets should be dissolved in half a glass of water. When dissolved in water, a whitish solution is formed that should be taken immediately.

Taking this medicine

- Flexilev cartridges should only be used with MyFID dose dispenser. Your doctor will adjust the dosage to you by using functions of the dose dispenser.
- The tablets should be taken at regular time intervals. The dose dispenser has a function that reminds you and facilitates for you to remember to take your tablets.
- The dose dispenser registers doses taken and has a rating system of your symptoms from which data can be transferred to your doctor.
- The dose dispenser is loaded with a cartridge containing 750 dispersible tablets. At normal dosage one cartridge lasts 1–2 weeks. The foil bag should be removed before the cartridge is placed into the dose dispenser.

The tablets should be taken as follows;

- The dose dispenser MyFID alerts and a message switches between "TAKE DOSE" and a specified time. Press this message. You can take your dose 15 minutes before to 15 minutes after the specified time. Before you take a dose, turn the dose dispenser upside down. This to allow any jammed tablets to detach. After pressing "TAKE DOSE" a window will open. Adjust the dose upwards or downwards if needed and recommended by your doctor. Please note that your doctor will set how much you are allowed to adjust. Then press "TAKE DOSE" again. The tablets are counted and collected in a container inside the dose dispenser (the collector). Keep the dose dispenser MyFID upright during the tablet count.

The mini tablets are now fed into the container inside the dose dispenser. When the tablet count has ended, a new window will open. Keep the dose dispenser upright above a glass and press "EJECT",

and the mini tablets will be ejected into the glass/cup. Keep the dose dispenser upright until the dispensing is finished.

- After the tablets have been ejected, the tablets should be dissolved in half a glass of water. When dissolved in water, a whitish solution is formed that should be taken immediately.
- Doses above 100 mg, i.e. above 20 tablets will be counted and ejected in two rounds. You will be asked to eject the tablets twice. Follow the instructions on the screen. Tablets in the second round will be dispensed only after you pressed "EJECT".
- For further information, see the manual of the dose dispenser.

Flexilev with food and drink

Some patients may experience slightly less effect of Flexilev if the tablets are taken with protein rich food. Meat, fish, eggs, beans, milk and cheese contain protein. If possible, take Flexilev 30 minutes before or 1 hour after a meal.

If you have not had levodopa before

100 mg (20 dispersible tablets) three times a day. Your doctor will gradually increase the dose using an escalation scheme in the dose dispenser.

Patients with unsatisfactory effect at the end of dose interval (*wearing off*) may be helped by dividing the dosage into smaller, more frequent dosing, however, without altering the daily dose. Your doctor will help you to adjust the dose and dosage frequency.

If you have had levodopa before

your doctor will ask you to stop taking your medicine for Parkinson's disease before you start taking Flexilev.

Use in children and adolescents

The safety of Flexilev in patients under 18 years has not been established. There is no relevant use of Flexilev for children and adolescents for the treatment of Parkinson's disease.

If you take more Flexilev than you should

If you take too many tablets see your doctor immediately.

If you forget to take Flexilev

Do not take a double dose to make up for a forgotten dose.

If you stop taking Flexilev

Do not stop taking Flexilev without talking to your doctor. When you stop taking Flexilev you may experience muscles stiffness, high temperature (fever) and mental changes.

If you temporarily have to stop your treatment with Flexilev, e.g. before surgery, you should continue with your regular dosage as soon as possible.

If you have any further questions on 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.

Stop taking Flexilev and see your doctor straight away if notice any of the following side effects:

- allergic reaction, the signs may include hives (nettle rash), itching, rash, swelling of your face, lips, tongue or throat. This may cause difficulty in breathing or swallowing
- chest pain
- uneven (irregular) heartbeat or palpitations
- bleeding from your gut which may be seen as blood in your faeces or darkened faeces (gastro-intestinal bleeding)

- blood problems, the signs may include pale skin (pallor), tiredness, fever, sore throat or mild bruising and prolonged bleeding after injury
- muscle stiffness, severe inability to sit still, high fever, sweating, increased salivation and impaired consciousness (neuroleptic malignant syndrome)
- mental changes including delusions, hallucinations and depression with or without suicidal tendencies
- fits (convulsions).

Other side effects that may occur:

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

- urinary tract infections
- palpitations, irregular heartbeat

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

- loss of appetite (anorexia)
- anxiety, confusion, drowsiness, sleeplessness, feeling of well-being (euphoria), psychotic episodes including paranoid ideation, feeling of stimulation
- movement disorders (dyskinesia), a disorder characterised by sudden involuntary movements (chorea), dizziness, muscle tone disorder (dystonia), movement disorders caused from outside the nervous system, sudden changes in Parkinson's symptoms ("on-off" symptoms), slowdown in movements during "on-off" periods (bradykinesia), tendency to faint
- a drop in blood pressure caused e.g. by getting up too quickly from a sitting or lying position, sometimes accompanied by dizziness (orthostatic hypotension)
- nausea, vomiting, bitter taste

Uncommon (may affect up to 1 in 100 people):

- weight loss or weight gain
- excitement (agitation), dream abnormalities
- disturbance of muscle coordination (ataxia), increase in hand tremors, headache, sudden loss of consciousness
- increase in blood pressure, hot flushes
- hoarseness, abnormal breathing pattern
- constipation, diarrhea, increased salivation, difficulties in swallowing, flatulence, abdominal pain and discomfort, dry mouth
- muscle spasms, convulsions, muscle twitching
- dark urine
- loss of strength (asthenia), weakness, feeling of being unwell (malaise)
- fluid accumulation (oedema)
- tiredness

Rare (may affect up to 1 in 1,000 people):

- malignant melanoma
- a blood disorder (lack of white blood cells) accompanied by an increased susceptibility to infections (leukopenia), anaemia, a blood disorder (lack of blood platelets) accompanied by bruising and a tendency to bleed (thrombocytopenia)
- sudden build-up of fluid in the skin and mucous membranes (e.g. throat and tongue), breathing difficulties and/or itching and skin rash, often appearing as an allergic reaction (angioedema)
- impaired ability to think, disorientation, increased sexual desire, grinding of teeth
- a serious condition as a result of using neuroleptics, which may manifest as muscle stiffness, a severe inability to sit still, high fever, sweating, increased salivation and impaired consciousness (neuroleptic malignant syndrome),
- feelings of prickling, tingling and itchiness without any apparent cause, epileptic seizures, dementia
- blurred vision, spasm of the orbicularis oculi muscle surrounding the eye, activation of a pre-existing Horner's syndrome (an eye disorder), double vision, dilated pupils, a deterioration in eye movements, inflammation of the veins, blushing
- breathlessness, hiccups
- heartburn (dyspepsia), dark saliva, stomach and intestinal bleeding, burning tongue, duodenal ulcers

- hypersensitivity reactions including skin rash with severe itching and the formation of wheals (urticaria), itching, facial redness, hair loss, skin rash, increased sweating, dark sweat
- in children, allergy-related bleeding in the skin and gastrointestinal tract wall (Schönlein- Henoch purpura)
- lockjaw
- urine retention, involuntary passing of urine
- persistent erection (priapism)
- chest pain

Very rare (may affect up to 1 in 10,000 people):

- a very serious blood disorder (lack of white blood cells) accompanied by sudden high fever, severe sore throat and mouth ulcers (agranulocytosis)
- drowsiness and constant daytime fatigue/ sudden attacks of sleep
- numbness

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

- muscle twitching
- Inability to resist the impulse to perform an action that could be harmful, such as:
 - Strong impulse to gamble excessively despite serious personal or family consequences.
 - Altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive.
 - Uncontrollable excessive shopping or spending
 - Binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger)
 - Craving for large doses of Flexilev in excess of that required to control motor symptoms, known as dopamine dysregulation syndrome. Some patients experience severe abnormal involuntary movements (dyskinesias), mood swings or other side effects after taking large doses of Flexilev.

Tell your doctor if you experience any of these behaviors; they will discuss ways of managing or reducing the symptoms.

If any symptoms persist or you experience any other side effects please tell your doctor or pharmacist. It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flexilev

- Keep this medicine out of the sight and reach of children.
- Store in the original package in order to protect from light and moisture.
- After the foil bag has been opened, the cartridge should be used within 3 months. Store below 30°C.
- Do not use this medicine after the expiry date which is stated on the cartridge after EXP. 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 Flexilev contains

- The active substances are levodopa and carbidopa.
- The other ingredients are microcrystalline cellulose, colloidal anhydrous silica, maize starch, sodium starch glycolate, magnesium stearate.

What Flexilev looks like and contents of the pack

Flexilev is white, spherical, dispersible tablets with a diameter of about 3 mm.

Flexilev is provided in a cartridge which is packaged in a sealed aluminium foil bag. Each cartridge contains 750 dispersible tablets

Pack size: 10x750 dispersible tablets.

Flexilev cartridge should be used with a dose dispenser. Only MyFID dose dispenser should be used. The dispenser is provided separately from the Flexilev tablets.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Desitin Arzneimittel GmbH
Weg beim Jaeger 214
22335 Hamburg
Germany

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