Patient package insert according to Pharmacists' Regulations (Preparations) - 1986
This medicine can be sold with a physician's prescription only

TRAMADEX® FLASHTAB®
Tablets soluble in mouth, 50 mg

Each soluble tablet contains tramadol hydrochloride 50 mg.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

This medicine is not intended for children under the age of 14 years.

Opioid medicines can cause addiction (mainly with prolonged use), and potential abuse and overdose are possible. The reaction to overdose can be slow breathing and even death.
Make sure that you know the name of the medicine, the dosage you are taking, how often you take it, the duration of treatment, and its side effects and potential risks.
Additional information about the risk of dependence and addiction can be found at:
https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/risk/DocLib/opioids_en.pdf

Taking this medicine with benzodiazepines, other central nervous system depressants (including street drugs) or alcohol can cause severe drowsiness, breathing problems (respiratory depression), coma and death.

1. What is the medicine intended for?
Tramadex Flashtab is intended for the treatment of moderate to severe pain.

Therapeutic group: opioids.
Tramadol, the active ingredient in **Tramadex Flashtab**, is a painkiller belonging to the class of medicines called opioids and it acts on the central nervous system. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

2. Before using the medicine
Do not use the medicine:

- if you are hypersensitive (allergic) to the active ingredient (tramadol hydrochloride) or to any of the other ingredients this medicine contains (see section 6)
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions)
- if you are taking monoamine oxidase (MAO) inhibitors (certain medicines to treat depression) or have taken them in the last 14 days before taking **Tramadex Flashtab** (see the section "Drug interactions")
- if you are an epileptic and your fits are not adequately controlled by your treatment
- as a substitute in drug withdrawal

Special warnings regarding the use of the medicine
Before the treatment with Tramadex Flashtab, tell the doctor if:

- you think that you are or have ever been dependent on other pain relievers (opioids), alcohol, prescription medicines, or any illegal drug.
- you have previously suffered from withdrawal symptoms such as: agitation, anxiety, shaking or sweating when you have stopped taking alcohol or drugs.
- you feel a need to take more **Tramadex Flashtab** to get the same level of pain relief; this may mean you are starting to become tolerant to the effects of this medicine and are becoming addicted to it. Contact your doctor who will discuss your treatment and may change your dose or switch you to another pain reliever.
- you suffer from consciousness disorders (if you feel that you are going to faint).
- you are in a state of shock (cold sweat may be a sign of this).
- you suffer from increased pressure on the brain (this may happen after a head injury or brain disease).
- you have difficulty in breathing.
- you have epilepsy or a tendency to have convulsions, because the risk of convulsions may increase.
- you suffer from depression and you are taking antidepressants as some of them may interact with tramadol (see "Drug interactions").
- you suffer from a liver or kidney disease.

Sleep-related breathing problems
Tramadex Flashtab contains an active ingredient that belongs to a group of medicines called opioids. Opioids can cause sleep-related breathing problems, for example pauses in breathing during sleep (shallow breathing/sleep apnea) and sleep-related hypoxemia (low level of oxygen in the blood).
The risk of experiencing pauses in breathing during sleep is dependent on the dose of opioid. Your doctor may consider decreasing your total opioid dose if you experience pauses in breathing during sleep.

There is a small risk of experiencing serotonin syndrome that can occur after having taken tramadol in combination with certain antidepressants or tramadol alone. Seek medical advice immediately if you have any of the symptoms related to this serious syndrome (see section 4 “Side effects”).
Epileptic fits have been reported in patients taking tramadol at the recommended dose level. The risk may be increased when doses of tramadol exceed the recommended upper daily dose limit (400 mg).

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be taking it for, when it is appropriate to stop, and how to do this safely.
Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, please speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, palpitations, increased blood pressure, nausea or vomiting, diarrhea, loss of appetite, shaking or sweating. Your doctor will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking a higher dose or more frequent doses of opioids may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Tramadol is transformed in the liver by an enzyme. Some people have a variation of this enzyme and this can affect them in different ways. Some people may not get enough pain relief, while other people are more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and contact your doctor immediately: slow or shallow breathing, confusion, sleepiness, small pupils, nausea or vomiting, constipation, lack of appetite.

Talk to your doctor if you experience any of the following symptoms while taking **Tramadex Flashtab:** Extreme fatigue, lack of appetite, severe abdominal pain, nausea, vomiting or low blood pressure. This may indicate that you have adrenal insufficiency (low cortisol levels). If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

Drug interactions
If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Tramadex Flashtab should not be taken together with MAO inhibitors (certain medicines for the treatment of depression), or if you have taken them during the 14 days before taking **Tramadex Flashtab**.
The pain-relieving effect of **Tramadex Flashtab** may be reduced and the length of time it acts may be shortened, if you take it together with medicines that contain:
- carbamazepine (for epileptic fits)
- ondansetron (to prevent nausea)

Your doctor will tell you whether you should take **Tramadex Flashtab**, and which dose.

The risk of side effects may increase if you are taking:
- other pain relievers such as morphine and codeine (also for cough relief) or alcohol while you are taking **Tramadex Flashtab**. You may feel drowsy or feel that you might faint. If this happens tell your doctor.
- Concomitant use of **Tramadex Flashtab** and tranquillizers or sleeping pills (e.g. benzodiazepines), increases the risk of drowsiness, difficulties in breathing (respiratory depression), and coma, and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor prescribes **Tramadex Flashtab** together with sedating medicines the dose and the duration of the concomitant treatment should be limited by your doctor. Please tell your doctor about all sedating medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to ask friends or relatives to be aware of the signs and symptoms. Contact your doctor if you experience these symptoms.
- medicines which may cause convulsions (epileptic fits), such as certain antidepressants or antipsychotics. The risk of having a fit may increase if you take **Tramadex Flashtab** at the same time. Your doctor will tell you whether **Tramadex Flashtab** is suitable for you.
- certain medicines for depression. **Tramadex Flashtab** may interact with them and you may experience serotonin syndrome (see section 4 "Side effects").
- coumarin anticoagulants (medicines for blood thinning), e.g. warfarin. The effect of these medicines on blood clotting may be affected and bleeding may occur.

Use of the medicine and food
Food does not influence the effect of **Tramadex Flashtab**.

Use of the medicine and alcohol consumption

Do not drink alcoholic beverages during treatment with **Tramadex Flashtab**, as its effect may be intensified.

Children and adolescents
Use of **Tramadex Flashtab** in children with breathing problems:
Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

Pregnancy, breastfeeding, and fertility
Do not take **Tramadex Flashtab** if you are pregnant or think you might be pregnant, unless you have discussed this with your doctor, and the benefits of treatment outweigh the risk of harm to the baby. If you take **Tramadex Flashtab** during pregnancy, your baby may become dependent and experience withdrawal symptoms after birth that may need to be treated.
Do not take **Tramadex Flashtab** while you are breastfeeding because tramadol passes into breast milk and may affect your baby.
Based on human experience, tramadol does not influence female or male fertility.

Driving and using machines
Tramadex Flashtab may cause drowsiness, dizziness, and blurred vision, and therefore may impair your reactions. If you feel that your reactions are affected, do not drive a car or other vehicles, do not operate electric tools or machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
Do not drive while taking this medicine until you know how it affects you.
Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.
As for children, they should be warned about riding a bicycle or playing near roads, etc.

Important information about some of the ingredients of the medicine
This medicine contains 20 mg aspartame per tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria, a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to use the medicine?
Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only.
The dosage should be adjusted to the intensity of your pain and your individual pain sensitivity.
In general, the lowest pain-relieving dose should be taken. Do not take more than 400 mg tramadol hydrochloride daily, unless your doctor has instructed you to do so.

Unless otherwise prescribed by your doctor, the usual dosage is:

Adults and adolescents from the age of 14 years
One or two tablets (equivalent to 50-100 mg tramadol hydrochloride), every 4-6 hours.
Your doctor may prescribe a different dosage that is more appropriate for you, if necessary.

Children
Tramadex Flashtab is not intended for children below the age of 14 years.

Elderly patients

In elderly patients (above 75 years), the excretion of tramadol from the body may be delayed. If this applies to you, your doctor may recommend increasing the intervals between doses.

Severe liver or kidney disease (insufficiency)/dialysis patients
Patients with severe liver and/or kidney insufficiency should avoid taking **Tramadex Flashtab**. If in your case the insufficiency is mild or moderate, your doctor may recommend increasing the intervals between doses.

Do not exceed the recommended dose.

How and when should you take **Tramadex Flashtab**?
Tramadex Flashtab is for sucking. Do not split, crush, chew, or swallow the tablet. If necessary you may dissolve each tablet in half a glass of water. You may take the tablet on an empty stomach or with a meal.

How long should you take **Tramadex Flashtab**?
Your doctor should have discussed with you how long the course of treatment will last and arranged a plan for stopping treatment. This plan outlines how to gradually reduce the dose until you stop taking the medicine.

If you have accidently taken a higher dosage
If you have taken an additional dose by mistake, this will generally have no negative effects. You should take your next dose as prescribed.
If you (or someone else) take a lot of **Tramadex Flashtab** at once you should go to a hospital or see a doctor straight away. Bring the medicine package with you.
Signs of an overdose include very small pupils, vomiting, fall in blood pressure, fast heartbeat, collapse, unconsciousness, convulsions, and breathing difficulties or shallow breathing.

If you forgot to take the medicine
If you forget to take **Tramadex Flashtab**, pain is likely to return. Do not take a double dose to make up for a forgotten dose; simply continue taking the medicine as before.

If you stop taking the medicine
Do not suddenly stop taking this medicine. If you want to stop taking your medicine, consult your doctor first. Your doctor will explain to you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum.
Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, palpitations, increased blood pressure, nausea or vomiting, diarrhea, shaking or sweating may occur if you suddenly stop taking this medicine.
Continue with the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects
Like any medicine, the use of **Tramadex Flashtab** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

You should see a doctor immediately if you experience symptoms of an allergic reaction such as swollen face, tongue and/or throat, and/or difficulty swallowing, or hives (red bruises on the skin) together with difficulties in breathing.

Very common side effects (effects that occur in more than 1 in 10 users):
- dizziness.
- nausea.

Common side effects (effects that occur in 1-10 out of 100 users):
- headaches, drowsiness.
- fatigue.
- constipation, dry mouth, vomiting.
- sweating.

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):
- effects on the heart and blood circulation (palpitation, fast heartbeat, feeling faint or collapse). These side effects occur particularly in patients in an upright position or under physical strain.
- urge to vomit (retching), stomach trouble (e.g. feeling of pressure in the stomach, bloating), diarrhea
- skin reactions (e.g. itching, rash)

Rare side effects (effects that occur in 1-10 out of 10,000 users):
- allergic reactions (e.g. difficulty in breathing, wheezing, swelling of skin) and shock (sudden failure of blood circulation)
- slow heartbeat
- increase in blood pressure
- abnormal sensations (e.g. itching, tingling, numbness), trembling, epileptic fits, muscle twitches, uncoordinated movement, transient loss of consciousness (syncope), speech disorders
- Epileptic fits have occurred mainly at high doses of tramadol or when tramadol was taken at the same time as other medicines which may induce fits.
- changes in appetite
- hallucination, confusion, sleep disorders, anxiety and nightmares
- Psychological complaints may appear after treatment with **Tramadex Flashtab**. Their intensity and nature may vary (according to the patient's personality and length of therapy). These may appear as a change in mood (mostly high spirits, occasionally irritated mood), changes in activity (usually suppression, occasionally increase) and decreased cognitive and sensory perception (being less aware and less able to make decisions, which may lead to errors in judgement).
- blurred vision, excessive dilation of the pupils, constriction of the pupils
- slow breathing, shortness of breath
- Worsening of asthma has been reported; however, it has not been established whether it was caused by tramadol. If the recommended doses are exceeded, or if other medicines that depress brain function are taken at the same time, breathing may slow down.
- muscle weakness
- passing urine with difficulty or pain, passing less urine than normal

Very rare side effects (effects that occur in less than 1 in 10,000 users):
- hepatic enzyme increased

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- blood sugar level is too low
- hiccups
- Serotonin syndrome, that can manifest as mental status changes (including symptoms such as agitation, hallucinations, coma), and other effects, such as fever, increase in heart rate, unstable blood pressure, involuntary twitching, muscular rigidity, lack of coordination and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea) (see section 2 "Before using the medicine")
- dependence and addiction (see below 'How do I know if I am addicted')

Drug withdrawal:
When you stop taking **Tramadex Flashtab**, you may experience withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, anxiety, palpitations, increased blood pressure, nausea, diarrhea, shaking, sweating.

How do I know if I am addicted?
If you notice any of the following signs while you are taking **Tramadex Flashtab**, this could be a sign of addiction:

- You feel you need to take the medicine for longer than advised.
- You feel you need to use more than the recommended dose.
- You are using the medicine for reasons other than prescribed.
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important that you talk to your doctor.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 25°C, in the original package.

6. Additional information

In addition to the active ingredient, the medicine also contains:
Mannitol, crospovidone, aspartame, ethylcellulose, mint rootbeer flavouring, copovidone, silicon dioxide, magnesium stearate.

What the medicine looks like and what the package contains:
round, white tablet with "T" debossed on one side, and "50" on the other.
Approved pack sizes: 2, 5, 7, 10, 14, 20, 28, 30, 40, 50, 56, 60, 100 tablets. Not all package sizes may be marketed.

Drug registration number at the national drug registry of the Ministry of Health:

132-15-31083-00
Revised in January 2023 according to MOH guidelines.
Manufacturer and registration holder: Dexcel® Ltd.
1 Dexcel St., Or Akiva 3060000, Israel