

# DUOCETZ FILM COATED TABLET

Paracetamol/ Tramadol Hydrochloride (325mg/37.50mg)

## What is in this leaflet

1. What DUOCETZ is used for
2. How DUOCETZ works
3. Before you use DUOCETZ
4. How to use DUOCETZ
5. While you are using it
6. Side effects
7. Storage and Disposal of DUOCETZ
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision

## What DUOCETZ is used for

DUOCETZ is used to treat moderate pain to severe pain.

## How DUOCETZ works

DUOCETZ have a combination of two pain relievers- paracetamol and tramadol hydrochloride (an opioid analgesic).

## Before you use DUOCETZ

### - When you must not use it

- You are less than 12 years old.
- You have slow or shallow breathing, or breathing problems.
- You are pregnant.
- You are breastfeeding.

You must not take DUOCETZ if you have previously had an allergic reaction (hypersensitivity) to tramadol hydrochloride or paracetamol, or to any other opioid pain relievers. Please tell your doctor if this applies to you. Hypersensitivity can be recognized for instance by skin rash, itching, shortness of breath or swollen face. If any of these occur, contact your doctor right away.

Do not give DUOCETZ to a child under 18 years of age that has just an operation to remove their tonsils or adenoid.

Do not take DUOCETZ if you are taking:

- Sleeping pills e.g. Hypnotics;
- Medicines that affect your mood or emotions e.g. narcotics and psychotropics drugs;
- Pain relievers that affect your central nervous system e.g. centrally acting analgesics and opioids;

- Antidepressants such as Monoamine Oxidase Inhibitors (MAO inhibitors) currently or within the last 14 days.

### *Pregnancy and lactation*

Please consult your doctor or if you are pregnant, planning for pregnancy or breast-feeding before using this medicine. Opioid medicine can slow the breathing of a newborn child. Prolonged use of DUOCETZ during pregnancy can cause withdrawal symptoms in your new-born baby that could be life-threatening if not recognized and treated. This risk is increased in the last trimester of pregnancy.

### *Breastfeeding*

You are not advised to take DUOCETZ if you are breastfeeding because DUOCETZ is excreted into breast milk.

### - Before you start to use it

Check with your doctor or pharmacist before taking DUOCETZ if you:

- Suffer from serious liver or kidney disease,
- Have diabetes,
- Are over 65 years of age,
- Have abdominal problems.
- Have a previous head injury,
- Have chronic alcoholism,
- Are pregnant or plan to become pregnant,
- Are breast-feeding,
- If you are taking any other medications including natural health products, prescription drugs, salicylates, other pain and fever relief medications or nonsteroidal anti-inflammatory drugs (NSAIDs).

This will help your doctor to decide whether you should use DUOCETZ and what extra care should be taken during its use.

### - Taking other medicines

Taking DUOCETZ with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepine.

Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Inform your doctor or pharmacist if you are taking any of the following medicines as DUOCETZ may affect how well they work:

- Monoamine Oxidase Inhibitors (MAOIS), used to treat mental conditions such as depression e.g. phenelzine, tranylcypromine. You should not take DUOCETZ with MAOIs or within 14 days of having last taken them;
- Selective Serotonin Reuptake Inhibitors (SSRI's), used to treat depression or Parkinson's Disease;
- Drugs used to treat depression e.g. mirtazapine; tricyclic antidepressants; trazadone;
- Triptans, used to treat migraines;
- 5-HT<sub>3</sub> receptor antagonists, used to treat nausea and vomiting;
- Medicines that slow down your central nervous system such as sedatives, sleeping pills, drugs used for surgery (anesthetics), tranquilizers (benzodiazepines), drugs used to treat certain mental conditions (psychotropic drugs), some strong painkillers (opioids), or alcohol;

- Antibiotics to treat infections, e.g. erythromycin, rifampin, linezolid, flucloxacillin;
- Anti-fungals used to treat fungal infection, e.g. ketoconazole;
- Anti-retrovirals used to treat HIV/AIDs, e.g. ritonavir;
- Phenytoin, used to treat epilepsy and some types of pain;
- Carbamazepine, used to treat epilepsy and some types of pain;
- Quinidine, used to treat heart conditions (antiarrhythmics);
- Warfarin like compounds, used to stop blood clotting (blood thinners);
- Drugs that slow down or reduce the conversion (metabolism) of this drug to its active form (CYP2D6 inhibitors); e.g. fluoxetine, paroxetine, amitriptyline, and bupropion;
- Cimetidine, used to treat heart burn and peptic ulcers.

### How to use DUOCETZ

DUOCETZ comes in the form of tablet to be taken by mouth. You can take DUOCETZ at any time of the day with or without food, Do not take more than the recommended dose of DUOCETZ. The lowest effective dose should be used for the shortest period of time.

#### - How much to use

Adults (including elderly) and children over 16 years:

Take 1 to 2 tablets every 4 to 6 hours as needed for pain relief.

Do not take more than 8 tablets in a 24-hour period.

Do not take DUOCETZ if you have severe liver problem.

Tell your doctor if you have a kidney disorder (a creatinine clearance of less than 30 mL/min). Do not take more than 2 tablets every 12 hours.

#### - When to use it

Always take DUOCETZ exactly as your doctor has told you. You should check with your doctor if you are not sure.

#### - How long to use it

Continue taking DUOCETZ for as long as your doctor recommends.

#### - If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

#### - If you use too much (overdose)

Tell your doctor immediately if you have taken too much DUOCETZ, especially if you have any of the following symptoms:

Breathing difficulties with slow or shallow breathing and/ or fits (seizures), irritation and discomfort in the stomach and gut, loss of appetite, nausea, vomiting, feeling unwell, unusually pale colour and sweating. Cases of abnormal electrical conduction in the heart have been reported.

Your doctor will take the necessary measures.

Accidental swallowing of DUOCETZ tablet, especially by children, can result in breathing difficulties, with slow or shallow breathing, and/or fits (seizures). Deaths have been reported.

### While you are using DUOCETZ

#### - Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking DUOCETZ.

Tell your doctor immediately if you become pregnant while taking this medication

#### - Things you must not do

Do not take more than your recommended dose.

#### Discontinuation:

Stopping the DUOCETZ tablet too quickly may cause some side effects, so your doctor may ask you to gradually stop taking your medication over

several days. To get the full benefit from your treatment, it is important to take DUOCETZ tablet as prescribed.

#### - Things to be careful of

Tramadol is not to be used during breast-feeding. Small amounts of tramadol is excreted into breast milk. On a single dose it is usually not necessary to interrupt breast-feeding. If you are taken DUOCETZ when you are breastfeeding, seek immediate medical attention if you notice your baby has any changes in their breathing (such as weak, difficult or fast breathing).

#### Serotonin syndrome:

DUOCETZ may cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

#### Adrenal insufficiency:

Long-term use of DUOCETZ may cause adrenal insufficiency, a potentially life-threatening condition that may present with non-specific symptoms and sign such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

#### Infertility:

Long-term use of DUOCETZ may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Opioids can be abused and misused, and you are at risk for opioids addiction, even if you take your dose as prescribed.

Tell your doctor if you:

- Have an allergic reaction (characterized by significant skin rash, itching, hives, difficulty breathing, and/or swollen face) while taking codeine or other opioids).
- Taking other medicines, which contain tramadol or acetaminophen.

- Taking any medicines, because taking some medicines together with DUOCETZ may increase your risk of fits (seizures).
- Have asthma, any history of serious breathing problems or if you experience breathing difficulties, with slow or shallow breathing.
- DUOCETZ can cause low levels of oxygen in the blood and a problem called sleep apnea (stopping breathing from time to time whilst sleeping). Tell your doctor if you have a history of sleep apnea or if anyone notices you stop breathing from time to time whilst sleeping.
- DUOCETZ is not for use in children under 12 years old as it may result in breathing difficulties, with slow or shallow breathing, that could lead to death.
- Taking any drugs that slow down your central nervous system (for example, drugs that make you sleepy, reduce anxiety or decrease awareness). Taking these kinds of drugs with DUOCETZ can cause severe drowsiness, decreased awareness and breathing difficulties, with slow or shallow breathing.
- Have recently suffered from a head injury or severe headaches associated with vomiting.
- Have a history of substance dependence or abuse of drugs, alcohol or any opioid painkillers.
- Have a history of mental health problems.
- Want to stop taking DUOCETZ. You may become dependent on DUOCETZ and may need to reduce the dose of DUOCETZ slowly to avoid withdrawal symptoms.
- Stop taking DUOCETZ and tell your doctor immediately if you experience skin rash, especially:
  - A red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (Acute generalized exanthematous pustulosis).
  - A life-threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis).
  - A severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and

genitals (Stevens-Johnson syndrome).

- Some patients taking this medicine may experience low levels of sodium in the blood (hyponatremia). Symptoms of low blood sodium may include nausea and vomiting, headaches, feeling confused, feeling very tired, feeling restless, feeling irritable, muscle weakness, spasms or cramps and seizures. Elderly patients and patients taking other medicines that lower sodium in the blood are most at risk for this side effect. If you get any of this symptom while taking DUOCETZ, tell your doctor immediately.
- Tell your doctor if you have problems with or have had surgery on your gall bladder or bile duct so you can be monitored for potential development of acute pancreatitis (inflamed pancreas).
- Opioids can cause a high level of the hormone ‘prolactin’ and low levels of sex hormones in the blood. The effects of these hormone changes may include:
  - In females – unexpected production of breast milk; loss of menstrual periods
  - In males – enlarged breasts; difficulty getting and keeping an erection (impotence)
  - In females or males – decreased sex drive; infertility.

Tell your doctor if you notice any of these symptoms. You may need blood tests, and your doctor may tell you to stop using DUOCETZ.

#### WARNING

This preparation contains  
PARACETAMOL.  
Do not take any other paracetamol  
containing medicines at the same  
time.

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

#### Alcohol

You should not take DUOCETZ tablet with any alcohol-containing beverages. Also, you should tell your doctor if you drink alcohol regularly, or have a history of alcoholism.

*Driving and using machines* DUOCETZ may make you feel tired, dizzy or drowsy. If this happens, do not drive or use any machines.

#### Side effects

Like all medicines, DUOCETZ can cause side effects, although not everybody gets them. Tell your doctor if you notice any of the following side effects while using DUOCETZ:

#### Very common

- Nausea

#### Common

- Loss of appetite, difficulty sleeping, dizziness, headache, feeling sleepy, vomiting, constipation, diarrhea, indigestion, dry mouth, stomach discomfort, itching, increased sweating, feeling tired, hot flushes, stomach pain, wind, rash.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AE- FI)].

#### Storage and Disposal of DUOCETZ

##### - *Storage*

Keep out of the reach and sight of children.

Store below 30°C in the original package, away from direct sunlight.

Because of the risks associated with accidental ingestion, misuse, and abuse, advise patients to store DUOCETZ securely, in a location not accessible by others.

Do not use DUOCETZ tablet after the expiry date, even if it has been stored properly.

##### - *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**Product Description**

- What it looks like

Odorless, yellow colored, oblong film-coated tablet

- Ingredients

- Active ingredients

- Paracetamol 325mg
- Tramadol hydrochloride 37.50mg

- Inactive ingredients

Corn starch, povidone K30, sodium starch glycolate, microcrystalline cellulose 101, magnesium stearate pharmagrade, purified water and Opadry II yellow

- MAL number:

MALXXXXXXXXX

**Manufacturer**

MEGA LIFESCIENCES Public  
Company Limited  
515/1 Soi 8, Bangpoo Industrial Estate,  
Pattana 3 Road, Moo 4, Phraeksa,  
Samutprakarn 10280, Thailand.

**Product Registration Holder**

MEGA LIFESCIENCES SDN BHD  
B-28-02, The Ascent, Paradigm.  
No.1, Jalan SS7/26A, Kelana Jaya,  
47301 Petaling Jaya,  
Selangor, Malaysia.

**Date of revision**

13/04/2026

**Serial Number**

NPRA (R2) 25/097