CONTAINS PARACETAMOL

PACKAGE LEAFLET: INFORMATION FOR THE USER

IXPRIM® 37.5mg/325mg film-coated tablets

(tramadol hydrochloride/paracetamol)

Your medicine is available using the name Ixprim 37.5mg/325mg film-coated tablets but will be referred to as Ixprim throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine.

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

In this leaflet:

1. What Ixprim is and what it is used for

Ixprim is a combination of two analgesics, tramadol and paracetamol, which act together to relieve your pain.

Ixprim is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

Ixprim should only be taken by adults and adolescents over 12 years.

2. Before you take Ixprim

Do not take Ixprim

- if you have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) after taking tramadol or paracetamol or any of the other ingredients in Ixprim;
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression or Parkinson's disease) or have taken them in the last 14 days before treatment with Ixprim;
- if you suffer from a severe liver disorder;
- if you have epilepsy that is not adequately controlled on your current medicine.

Take special care with Ixprim if you

- take other medicines containing paracetamol or tramadol;
- have liver problems or liver disease or if you notice your eyes and skin turning yellow. This may suggest jaundice or problems with your bile ducts;
- have kidney problems;
- have severe difficulties in breathing for example asthma or severe lung problems;
- have epilepsy or have already experienced fits or seizures;
- have recently suffered from a head injury, shock or severe headaches associated with vomiting;
- are dependent on any medicines including those used to relieve pain, for example morphine;
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine;
- are going to have an anaesthetic. Tell your doctor or dentist that you are taking Ixprim.

If any of the above-mentioned points applied to you in the past or applies to you while you are taking Ixprim, please make sure your doctor knows. He/she can then decide whether you should continue to use this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Important: This medicine contains paracetamol and tramadol. Tell your doctor if you are taking *any other medicine containing paracetamol or tramadol*, so that you do not exceed the maximum daily doses.

You **must not** take Ixprim together with monoamine oxidase inhibitors ("MAOIs") (see section "Do not take Ixprim").

Ixprim is not recommended to be taken with the following:

- carbamazepine (a medicine commonly used to treat epilepsy or some types of pain such as severe pain attacks in the face called trigeminal neuralgia).
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

The risk of side effects increases, if you also take

- triptans (for migraine) or selective serotonin re-uptake inhibitors, "SSRIs" (for depression). If you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant) medicines used to lower blood pressure, antidepressants or medicines to treat allergies. You may feel drowsy or feel faint. If this happens, tell your doctor.
- antidepressants, anaesthetics, neuroleptics (medicines that affect the state of mind) or bupropion (to help stop smoking). The risk having a fit may increase. Your doctor will tell you whether Ixprim is suitable for you.
- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

The effectiveness of Ixprim may be altered if you also take

- metoclopramide, domperidone or ondansetron (medicines for treatment of nausea and vomiting),
- cholestyramine (medicine to reduce cholesterol in the blood),
- ketoconazole or erythromycin (medicines against infections).

Your doctor will tell you which medicines are safe to take with Ixprim.

Taking Ixprim with food and drink

Ixprim may make you feel drowsy. Alcohol may make you feel more drowsy, so it is best not to drink alcohol while you are taking Ixprim.

Pregnancy and breast-feeding

As Ixprim contains tramadol, you should not take this medicine during pregnancy. If you become pregnant during treatment with Ixprim, please consult your doctor before taking any further tablets.

Small amounts of tramadol may pass into the breast-milk. Therefore you should not take this medicine during breast-feeding.

Driving and using machines

Ixprim may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely.

Important information about some of the ingredients of Ixprim

Lactose is an ingredient in these tablets. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ixprim

Always take Ixprim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
You should take Ixprim for as short a time as possible.
The use in children below the age of 12 years is not recommended.
Unless otherwise prescribed by your doctor, the usual starting dose for adults and adolescents over 12 years is 2 tablets.
If required, further doses may be taken, as recommended by your doctor. The shortest time between doses must be at least 6 hours.
Do not take more than 8 Ixprim film-coated tablets per day.

Do not take Ixprim more often than your doctor has told you.

Your doctor may increase the time between doses

- if you are older than 75 years,
- if you have kidney problems or
- if you have liver problems.

Method of administration:

The tablets are for oral use.
Swallow the tablets whole with sufficient liquid. They should not be broken or chewed.

If you think that the effect of Ixprim is too strong (i.e. you feel very drowsy or have difficulty breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor.

If you take more Ixprim than you should:
In such cases please contact your doctor or pharmacist immediately even if you feel well. There is a risk of liver damage which may only show later.

If you forget to take Ixprim:
If you forget to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking the tablets as before.

If you stop taking Ixprim:
Generally there will be no after-effects when treatment with Ixprim is stopped. However, on rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly (see section 4. "Possible side effects"). If you have been taking Ixprim for some time, you should talk to your doctor if you want to stop because your body may have become used to it.

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

4. Possible side effects

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

Very common: more than 1 out of 10 persons treated;
- nausea,
- dizziness, drowsiness.

Common: less than 1 out of 10, but more than 1 out of 100 persons treated;
- vomiting, digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth,
- itching, sweating,
- headache, shaking,
- confusion, sleep disorders, mood changes (anxiety, nervousness, a feeling of high spirits).

Uncommon: less than 1 out of 100, but more than 1 out of 1,000 persons treated;
- increase in pulse or blood pressure, heart rate or heart rhythm disorders,
- difficulty or pain on passing water,
- skin reactions (for example rashes, hives),
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ear, involuntary muscle twitching,
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses,
- difficulty swallowing, blood in the stools,
- shivering, hot flushes, pain in the chest,
- difficulty breathing.

Rare: less than 1 out of 1,000, but more than 1 out of 10,000 persons treated;
- fits, difficulties in carrying out coordinated movements,
- addiction,
- blurred vision,
- transient loss of consciousness (syncope).

Unknown: cannot be estimated from the available data;
- decrease in blood sugar level.

The following are recognised side effects which have been reported by people using medicines that contain only tramadol or only paracetamol. However, if you experience any of these while taking Ixprim, you should tell your doctor:
- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting, changes in appetite, muscle weakness, slower or weaker breathing, mood changes, changes in activity, changes in perception, worsening of existing asthma.
- in some rare cases a skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment and see a doctor immediately. You must not take the medicine again.

In rare cases, using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it.

On rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may also get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in the ears (tinnitus). If you experience any of these complaints after stopping IXPRIM, please consult your doctor.

In exceptional cases blood tests may reveal certain abnormalities, for instance, low counts of blood platelets, which may result in nose bleeds or bleeding gums.

Use of Ixprim together with medicines used to thin the blood (e.g. phenprocoumon, warfarin) may increase the bleeding risk. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

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

5. How to store Ixprim

Keep out of the sight and reach of children.
Do not use after the expiry date (EXP) which is printed on the carton and the edge of the blister. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.
Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Ixprim contains
The active substances are tramadol hydrochloride and paracetamol.

Each film-coated tablet contains 37.5mg tramadol hydrochloride and 325mg paracetamol.

The other ingredients are:
Tablet core: powdered cellulose, pregelatinised starch, sodium starch glycolate (type A), maize starch and magnesium stearate.
Film-coating: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 6000, yellow iron oxide (E172), propylene glycol and talc.

What Ixprim looks like and contents of the pack
Ixprim are pale yellow, film-coated tablets, marked with the manufacturer's logo on one side and marked 'T5' on the other side.

Ixprim is available in blister packs containing 60 film-coated tablets.

Manufacturer
Manufactured by: Grünenthal GmbH,
Zieglerstrasse 6, 52078 Aachen, Germany.

Procured from within the EU by the Parallel Product Authorisation holder:
Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd,
Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

PPA No: 1151/139/1

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

In this leaflet:

1. What Ixprim is and what it is used for

Ixprim is a combination of two analgesics, tramadol and paracetamol, which act together to relieve your pain.

Ixprim is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

Ixprim should only be taken by adults and adolescents over 12 years.

2. Before you take Ixprim

Do not take Ixprim

- if you have had an allergic reaction (for instance skin rash, swelling of the face, wheezing or difficulty breathing) after taking tramadol or paracetamol or any of the other ingredients in Ixprim;
- in acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect mood and emotions);
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression or Parkinson's disease) or have taken them in the last 14 days before treatment with Ixprim;
- if you suffer from a severe liver disorder;
- if you have epilepsy that is not adequately controlled on your current medicine.

Take special care with Ixprim if you

- take other medicines containing paracetamol or tramadol;
- have liver problems or liver disease or if you notice your eyes and skin turning yellow. This may suggest jaundice or problems with your bile ducts;
- have kidney problems;
- have severe difficulties in breathing for example asthma or severe lung problems;
- have epilepsy or have already experienced fits or seizures;
- have recently suffered from a head injury, shock or severe headaches associated with vomiting;
- are dependent on any medicines including those used to relieve pain, for example morphine;
- take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine;
- are going to have an anaesthetic. Tell your doctor or dentist that you are taking Ixprim.

If any of the above-mentioned points applied to you in the past or applies to you while you are taking Ixprim, please make sure your doctor knows. He/she can then decide whether you should continue to use this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Important: This medicine contains paracetamol and tramadol. Tell your doctor if you are taking *any other medicine containing paracetamol or tramadol*, so that you do not exceed the maximum daily doses.

You **must not** take Ixprim together with monoamine oxidase inhibitors ("MAOIs") (see section "Do not take Ixprim").

Ixprim is not recommended to be taken with the following:

- carbamazepine (a medicine commonly used to treat epilepsy or some types of pain such as severe pain attacks in the face called trigeminal neuralgia).
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

The risk of side effects increases, if you also take

- triptans (for migraine) or selective serotonin re-uptake inhibitors, "SSRIs" (for depression). If you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- tranquillizers, sleeping pills, other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant) medicines used to lower blood pressure, antidepressants or medicines to treat allergies. You may feel drowsy or feel faint. If this happens, tell your doctor.
- antidepressants, anaesthetics, neuroleptics (medicines that affect the state of mind) or bupropion (to help stop smoking). The risk having a fit may increase. Your doctor will tell you whether Ixprim is suitable for you.
- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

The effectiveness of Ixprim may be altered if you also take

- metoclopramide, domperidone or ondansetron (medicines for treatment of nausea and vomiting),
- cholestyramine (medicine to reduce cholesterol in the blood),
- ketoconazole or erythromycin (medicines against infections).

Your doctor will tell you which medicines are safe to take with Ixprim.

Taking Ixprim with food and drink

Ixprim may make you feel drowsy. Alcohol may make you feel more drowsy, so it is best not to drink alcohol while you are taking Ixprim.

Pregnancy and breast-feeding

As Ixprim contains tramadol, you should not take this medicine during pregnancy. If you become pregnant during treatment with Ixprim, please consult your doctor before taking any further tablets.

Small amounts of tramadol may pass into the breast-milk. Therefore you should not take this medicine during breast-feeding.

Driving and using machines

Ixprim may make you feel drowsy and this may affect your ability to drive, or use tools and machines, safely.

Important information about some of the ingredients of Ixprim

Lactose is an ingredient in these tablets. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ixprim

Always take Ixprim exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
You should take Ixprim for as short a time as possible.
The use in children below the age of 12 years is not recommended.
Unless otherwise prescribed by your doctor, the usual starting dose for adults and adolescents over 12 years is 2 tablets.
If required, further doses may be taken, as recommended by your doctor. The shortest time between doses must be at least 6 hours.
Do not take more than 8 Ixprim film-coated tablets per day.

Do not take Ixprim more often than your doctor has told you.

Your doctor may increase the time between doses

- if you are older than 75 years,
- if you have kidney problems or
- if you have liver problems.

Method of administration:

The tablets are for oral use.
Swallow the tablets whole with sufficient liquid. They should not be broken or chewed.

If you think that the effect of Ixprim is too strong (i.e. you feel very drowsy or have difficulty breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor.

If you take more Ixprim than you should:
In such cases please contact your doctor or pharmacist immediately even if you feel well. There is a risk of liver damage which may only show later.

If you forget to take Ixprim:
If you forget to take the tablets, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue taking the tablets as before.

If you stop taking Ixprim:
Generally there will be no after-effects when treatment with Ixprim is stopped. However, on rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly (see section 4. "Possible side effects"). If you have been taking Ixprim for some time, you should talk to your doctor if you want to stop because your body may have become used to it.

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

4. Possible side effects

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

Very common: more than 1 out of 10 persons treated;
- nausea,
- dizziness, drowsiness.

Common: less than 1 out of 10, but more than 1 out of 100 persons treated;
- vomiting, digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth,
- itching, sweating,
- headache, shaking,
- confusion, sleep disorders, mood changes (anxiety, nervousness, a feeling of high spirits).

Uncommon: less than 1 out of 100, but more than 1 out of 1,000 persons treated;
- increase in pulse or blood pressure, heart rate or heart rhythm disorders,
- difficulty or pain on passing water,
- skin reactions (for example rashes, hives),
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ear, involuntary muscle twitching,
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapses,
- difficulty swallowing, blood in the stools,
- shivering, hot flushes, pain in the chest,
- difficulty breathing.

Rare: less than 1 out of 1,000, but more than 1 out of 10,000 persons treated;
- fits, difficulties in carrying out coordinated movements,
- addiction,
- blurred vision,
- transient loss of consciousness (syncope).

Unknown: cannot be estimated from the available data;
- decrease in blood sugar level.

The following are recognised side effects which have been reported by people using medicines that contain only tramadol or only paracetamol. However, if you experience any of these while taking Ixprim, you should tell your doctor:
- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting, changes in appetite, muscle weakness, slower or weaker breathing, mood changes, changes in activity, changes in perception, worsening of existing asthma.
- in some rare cases a skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or drop of blood pressure and fainting. If this happens to you, stop treatment and see a doctor immediately. You must not take the medicine again.

In rare cases, using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it.

On rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders. Very few people may also get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in the ears (tinnitus). If you experience any of these complaints after stopping IXPRIM, please consult your doctor.

In exceptional cases blood tests may reveal certain abnormalities, for instance, low counts of blood platelets, which may result in nose bleeds or bleeding gums.

Use of Ixprim together with medicines used to thin the blood (e.g. phenprocoumon, warfarin) may increase the bleeding risk. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

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

5. How to store Ixprim

Keep out of the sight and reach of children.
Do not use after the expiry date (EXP) which is printed on the carton and the edge of the blister. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.
If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return these to your pharmacist who will advise you further.
Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Ixprim contains
The active substances are tramadol hydrochloride and paracetamol.

Each film-coated tablet contains 37.5mg tramadol hydrochloride and 325mg paracetamol.

The other ingredients are:
Tablet core: powdered cellulose, pregelatinised starch, sodium starch glycolate (type A), maize starch and magnesium stearate.
Film-coating: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 6000, yellow iron oxide (E172), propylene glycol and talc.

What Ixprim looks like and contents of the pack
Ixprim are pale yellow, film-coated tablets, marked with the manufacturer's logo on one side and marked 'T5' on the other side.

Ixprim is available in blister packs containing 60 film-coated tablets.

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Repackaged by: Doncaster Pharmaceuticals Group Ltd,
Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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