For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

TOLDIN ER 600

1. Generic Name

Etodolac Extended Release Tablets I.P.

2. Qualitative and quantitative composition

Each film coated extended release tablet contains:
Etodolac I.P. ……..600 mg
Excipients……...q.s.
Colours: Yellow Oxide of Iron and Titanium Dioxide I.P.

The excipients used are Methocel, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Talcum, Colloidal Silicon Dioxide and Magnesium Stearate.

3. Dosage form and strength

Film Coated Extended Release Tablets 600 mg

4. Clinical particulars

4.1 Therapeutic indication

It is indicated for the treatment of Osteoarthritis and Rheumatoid Arthritis.

4.2 Posology and method of administration

For oral administration.
To be taken preferably with or after food
Undesirable effects may be minimised by using the shortest duration necessary to control symptoms
Dosage: As directed by the Physician.
Direction for use: Tablet should be swallowed whole & not to be broken, chewed or crushed.

Adults

One tablet daily, taken with a glass of water.
Toldin ER 600 mg tablets must be swallowed whole.
The safety of doses in excess of 600 mg per day has not been established.
No occurrence of tolerance or tachyphylaxis has been reported.

Elderly

The elderly are at increased risk of the serious consequences of adverse reactions. If an NSAID is considered necessary, the lowest effective dose should be used and for the shortest possible duration. The patient should be monitored regularly for GI bleeding during NSAID therapy.

Children

Use in children is not recommended.

4.3 Contraindications

• Hypersensitivity to etodolac or to any of the excipients.

• NSAIDs are contraindicated in patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angiooedema or urticaria) in response to ibuprofen, aspirin, or other non-steroidal anti-inflammatory drugs.

• History of gastrointestinal bleeding or perforation, related to previous NSAID's therapy.

• Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

• Severe heart failure, hepatic failure and renal failure

• During the last trimester of pregnancy

4.4 Special warnings and precautions for use

Undesirable effects may be minimized by using the minimum effective dose for the shortest duration necessary to control symptoms, and GI and cardiovascular risks below).

The use of Toldin ER 600 mg tablets with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Although non-steroidal anti-inflammatory drugs do not have the same direct effects on platelets as aspirin, all drugs which inhibit the biosynthesis of prostaglandins may interfere, to some extent, with platelet function. Patients receiving Toldin ER 600 mg Tablets who may be adversely affected by such actions should be carefully observed.

Elderly: The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation, which may be fatal.

Cardiovascular, Renal and Hepatic Impairment:

The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics and the elderly. Renal function should be monitored in these patients and the dose should be kept as low as possible. However, impairment of renal or hepatic functions due to other causes may alter drug metabolism; patients receiving concomitant long term therapy, especially the elderly, should be observed for potential side effects and their drug doses adjusted as needed, or the drug discontinued.

Patients on long-term treatment with Toldin ER 600 mg Tablets should be regularly reviewed as a precautionary measure e.g. for changes in renal function, haematological parameters, or hepatic function.

Cardiovascular and cerebrovascular effects:

Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Clinical trial and epidemiological data suggest that use of some NSAIDs (particularly at high doses and in long term treatment) may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). There are insufficient data to exclude such a risk for Etodolac.

Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with Etodolac after careful consideration. Similar consideration should be made before initiating longterm treatment of patients with risk factors for cardiovascular disease (e.g hypertension, hyperlipidaemia, diabetes mellitus and smoking).

Dermatological:
Serious skin reaction some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported very rarely in association with the use of NSAID's. Patients appear to be at highest risk of these reactions early in the course of therapy: the onset of the reaction occurring in the majority of cases within the first month of treatment. Etodolac ER tablets should be discontinued at the first appearance of skin rash, mucosal lesions, or any other signs of hypersensitivity.

Respiratory disorders:
Caution is required if Toldin ER 600 mg Tablets are administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients.

SLE and mixed connective tissue disease:
In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

Impaired female fertility:
The use of Toldin ER 600mg tablet may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Toldin ER 600mg tablet should be considered.

Gastrointestinal bleeding, ulceration and perforation:
GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.
The risk of bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particular if complicated with haemorrhage or perforation, and in the elderly. These patients should commence treatment on the lowest dose available.
Combination therapy with protective agents (e.g. misoprostal or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin or other drugs likely to increase gastrointestinal risk.
Patients with a history of GI toxicity, particularly when elderly, should report any unusual abdominal symptoms (especially GI bleeding) particularly in the initial stages of treatment.
Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants

such as warfarin, selective serotonin-reuptake inhibitors or anti-platelet agents such as aspirin.
When GI bleeding or ulceration occurs in patients receiving Etodolac, the treatment should be withdrawn.
NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated.

4.5 Drugs interactions

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding. Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin.
Since etodolac is extensively protein bound, it may be necessary to modify the dosage of other highly protein-bound drugs.
The concomitant administration of warfarin and Toldin ER 600 mg Tablets should not require a dosage adjustment of either drug, however it has rarely led to prolonged prothrombin times, therefore caution should be exercised when Toldin ER 600 mg Tablets are administered with warfarin.
Bilirubin tests can give a false positive result due to the presence of phenolic metabolites of etodolac in the urine.

Care should also be taken in patients treated with any of the following drugs as interactions have been reported in some patients including increase in serum levels of these compounds and associated toxicities:
• Anti-hypertensives: Reduced anti-hypertensive effect
• Mifepristone: NSAIDs should not be used for 8 – 12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
• Other analgesics including cyclooxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects.
• Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
• Diuretics: Reduced diuretic effect. Diuretics can increase the risk of nephrotoxicity of NSAIDs.
• Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.
• Lithium: Decreased elimination of lithium.
• Methotrexate: Decreased elimination of methotrexate.
• Cyclosporin: Increased risk of nephrotoxity.
• Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding.
• Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with tacrolimus.
•Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine.
There is evidence of an increased risk of haemarthroses and haematoma in HIV (+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen

4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

Pregnancy:

Drugs which inhibit prostaglandin biosynthesis may cause dystocia and delayed parturition as evidenced by studies in pregnant animals.

Congenital abnormalities have been reported in association with NSAID administration in man; however, these are low in frequency and do not appear to follow any discernible pattern. In view of the known effects of NSAIDs on the foetal cardiovascular system (risk of closure of the ductus arteriosus), use in the last trimester of pregnancy is contraindicated. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. NSAIDs should not be used during the first two trimesters of pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.

Lactation:

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breastfeeding.

4.7 Effects on ability to drive and use machines

Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

4.8 Undesirable effects

Gastrointestinal*:*

The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease have been reported following administration. Less frequently, gastritis has been observed. Pancreatitis has been reported very rarely.

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non-specific allergic reactions and anaphylaxis (b) respiratory tract reactivity comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angioedema and, more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Cardiovascular and cerebrovascular:

Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Clinical trial and epidemiological data suggests that use of some NSAID's (particularly at high doses and in long term treatment) may be associated with an increased risk of arterial thrombotic events (for example myocardial infarction of stroke).

Other adverse reactions reported less commonly include:

Endocrine disorders:

Oedema, pyrexia

Musculoskeletal connective tissue and bone disorders:

Weakness/malaise

Respiratory, thoracic and mediastinal disorders:
Dyspnoea
Neurological and special senses:
Visual disturbances, optic neuritis, headaches, paraesthesia, reports of aseptic meningitis (especially in patients with existing auto-immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation, depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue, tremor, insomnia, and drowsiness.
Dermatological:
Bullous reactions including Stevens-Johnson syndrome, and Toxic Epidermal Necrolysis (very rare). Photosensitivity.
Haematological:
Thrombocytopenia, neutropenia, agranulocytosis, aplastic anaemia and haemolytic anaemia.
Hepatic:
Abnormal liver function, hepatitis and jaundice.
Renal:
Bilirubinuria, urinary frequency, dysuria, nephrotoxicity in various forms including interstitial nephritis, nephrotic syndrome, renal failure.

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 any point of contact of Torrent Pharma available at:
http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.
By reporting side effects, you can help provide more information on the safety of this Medicine.

4.9 Overdose

a) Symptoms
Symptoms include headache, nausea, vomiting, epigastric pain, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, fainting, and occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible.

b) Therapeutic measure
Patients should be treated symptomatically as required.

Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose.

Good urine output should be ensured.

Renal and liver function should be closely monitored.

Patients should be observed for at least four hours after ingestion of potentially toxic amounts.

Frequent or prolonged convulsions should be treated with intravenous diazepam.

Other measures may be indicated by the patient's clinical condition.

5. Pharmacological properties

5.1 Mechanism of Action

All non-steroidal anti-inflammatory drugs (NSAIDs) have been shown to inhibit the formation of prostaglandins. It is this action which is responsible both for their therapeutic effects and some of their side effects. The inhibition of prostaglandin synthesis observed with etodolac differs from that of other NSAIDs.

5.2 Pharmacodynamic properties

ATC code: M01A B08

Pharmacotherapeutic group: anti-inflammatory and anti-rheumatic products, non-steroids, acetic acid derivatives and related substances

Inhibition of prostaglandin synthesis and COX-2 selectivity: All non-steroidal anti-inflammatory drugs (NSAIDs) have been shown to inhibit the formation of prostaglandins. It is this action which is responsible both for their therapeutic effects and some of their side effects. The inhibition of prostaglandin synthesis observed with etodolac differs from that of other NSAIDs.

In an animal model at an established anti-inflammatory dose, cytoprotective PGE concentration in the gastric mucosa have been shown to be reduced to a lesser degree and for a shorter period than other NSAIDs. This finding is consistent with subsequent in-vitro studies which have found etodolac to be selective for induced cyclo-oxygenase 2 (COX-2, associated with inflammation) over COX-1 (cytoprotective).

Furthermore, studies in human cell models have confirmed that etodolac is selective for the inhibition of COX-2.

The clinical benefit of preferential COX-2 inhibition over COX-1 has yet to be proven.

Anti-inflammatory effects: Experiments have shown etodolac to have marked anti-inflammatory activity, being more potent than several clinically established NSAIDs.

5.3 Pharmacokinetic properties

In man, etodolac is well absorbed following oral administration.

Etodolac is highly bound to serum proteins.

The elimination half-life averages seven hours in man. The primary route of excretion is in the urine, mostly in the form of metabolites.

In subjects receiving daily doses of Toldin ER 600 mg Tablets to steady state levels over a three day period, the peak plasma concentrations was 11.9 μg/ml at 7.8 hours.

6. Nonclinical properties

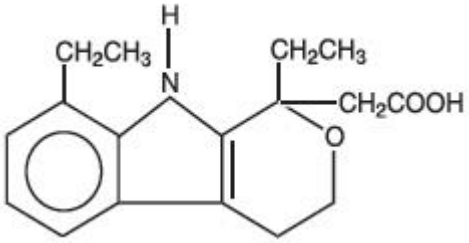
6.1 Animal Toxicology or Pharmacology

Preclinical data reveal no special hazard based on conventional studies of safety, pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

7. Description

Toldin ER 600 Tablets contain etodolac, which is a member of the pyranocarboxylic acid group of nonsteroidal anti-inflammatory drugs (NSAIDs). Etodolac is white crystalline compound, soluble in Ethanol (95%), in chloroform, in dimethylsulphoxide, in propylene glycol; practically insoluble in water.

The chemical name is (±) 1, 8-diethyl-1,3,4,9-tetrahydropyrano-[3,4-b]indole-1-acetic acid. The molecular weight is 287.37. Its molecular formula is $C_{17}H_{21}NO_3$ and it has the following structural formula:



Toldin ER Tablets are yellow coloured, capsule shaped, biconvex film coated extended release tablets having scored on one side. The excipients used are Methocel, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Talcum, Colloidal Silicon Dioxide and Magnesium Stearate.

8. Pharmaceutical particulars

8.1 Incompatibilities
Not applicable.

8.2 Shelf-life
Do not use later than the date of expiry.

8.3 Packaging information
Toldin ER 600 is packed in blister strips of 10 tablets.

8.4 Storage and handing instructions
Store protected from light and moisture, at a temperature not exceeding 30^0C.

9. Patient Counselling Information

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.

What in this leaflet:

9.1 What Toldin ER 600 is and what it is used for
9.2 What you need to know before you take Toldin ER 600
9.3 How to take Toldin ER 600
9.4 Possible side effects
9.5 How to store Toldin ER 600
9.6 Contents of the pack and other information

9.1 What Toldin ER 600 is and what it is used for
Toldin ER 600 is indicated for the treatment of Osteoarthritis and Rheumatoid Arthritis.

Toldin ER 600 is one of a group of medicines called “non-steroidal anti-inflammatory drugs” (NSAIDs) which are usually taken to relieve pain, inflammation and stiffness often caused by osteoarthritis or rheumatoid arthritis.

9.2 What you need to know before you take Toldin ER 600
Do not take Toldin ER 600:
- if you are allergic to etodolac or any of the other ingredients of this medicine
- if you have had an allergic reaction to other non-steroidal anti-inflammatory drugs such as aspirin or ibuprofen
- if you have experienced shortness of breath, rhinitis (blocked or runny nose) or urticaria (allergic skin reaction) when taking aspirin, ibuprofen or another non-steroidal anti-inflammatory drug
- if you have experienced gastrointestinal bleeding or perforation due to another non-steroidal anti-inflammatory drug
- if you have a peptic ulcer (ulcer in your stomach or duodenum) or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
- if you have severe heart failure, liver failure or kidney failure
- if you are in your last trimester of pregnancy.

Warnings and precautions
Talk to your doctor or pharmacist before taking Toldin ER 600.

- if you have problems with your heart, liver or kidneys or suffer from a blood disorder
- if you have a mixed connective tissue disorder such as lupus (SLE)
- if you suffer from or have had asthma or breathing difficulties
- if you suffer from fluid retention, (swelling of legs ankles and feet)
- if you suffer from heart failure or high blood pressure
- if you are taking long term-therapy with a medicine other than Toldin ER 600 , as your doctor will want to arrange regular check-ups, especially if you are elderly
- if you have disease that affects your digestion such as ulcerative colitis or Crohn's disease
- if you have heart problems, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- your doctor may carry out a number of blood, kidney function and liver function tests whilst you take Toldin ER 600
- if you are currently taking "water-pills" (diuretics)
- if any signs of gastrointestinal bleeding.

Medicines such as Toldin ER 600 may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

Children
Toldin ER 600 is not recommended for use in children.

Other medicines and Toldin ER 600
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other

medicines.

Toldin ER 600 can react with some medicines, which can cause unwanted effects or prevent the medicines from working properly

- drugs used to treat high blood pressure
- drugs used to thin the blood e.g. warfarin
- drugs called cardiac glycosides such as digoxin (used to treat heart problems)
- ciclosporin or tacrolimus (used after an organ transplant)
- methotrexate (used to treat rheumatoid arthritis or psoriasis)
- lithium (used to treat mental illness)
- mifepristone (used for the medical termination of pregnancy)
- other non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen
- corticosteroids such as prednisolone
- quinolone antibiotics (e.g. ciprofloxacin, levofloxacin, ofloxacin)
- antidepressants called SSRIs
- drugs used to stop blood clotting called antiplatelet agents (e.g. aspirin, dipyridamole, clopidogrel)
- diuretics ('water-pills')
- zidovudine (used to treat HIV infection).

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.

Toldin ER 600 may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.
Do not use Toldin ER 600 in the last trimester of pregnancy.
Toldin ER 600 should not be used during the first two trimesters of pregnancy unless your doctor advises you otherwise.

Toldin ER 600 have not been established as safe for use in breast-feeding mothers..

Driving and using machines
Toldin ER 600 may cause drowsiness, tiredness, dizziness and abnormal vision. Do not drive or operate machinery if you experience any of these symptoms.

Toldin ER 600 contains lactose and sunset yellow
Lactose is an ingredient in Toldin ER 600 . If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Toldin ER 600 contains orange yellow S E110. This may cause allergic reactions.

9.3 How to take Toldin ER 600
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 recommended dose is one tablet taken daily.
If you are elderly, your doctor will make sure you take the lowest dose for the shortest time, as you may be more likely to have the serious side effects.
Take with or after food. Swallow the tablet whole with water, do not crush or chew the tablets.

Use in children
Toldin ER 600 is not recommended for use in children.

If you take more Toldin ER 600 than you should
If you or anybody else take(s) too many tablets call your doctor or contact your nearest hospital immediately.
Symptoms of an overdose include headache, feeling and being sick, pain in the upper abdomen (above the navel), vomiting blood, disorientation, excitation, coma, drowsiness, dizziness, ringing in the ears (tinnitus), fainting and occasionally convulsions.

If you forget to take Toldin ER 600
If you forget to take a dose at the right time, take it as soon as you remember, unless it is nearly time for the next dose. Do not take a double dose to make up for a forgotten dose. Do not take more than one tablet in a single day.

If you stop taking Toldin ER 600
Do not stop taking Toldin ER 600 without your doctor's permission.

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

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

Stop taking and seek immediate medicinal attention if you experience any of the following
- epigastric pain (upper abdomen), vomiting blood, bloody stools, bleeding from the anus, inflammation of the colon, ulcers of mouth
- heartburn, indigestion abdominal pain
- allergic reactions such as rash, itching, blistering of skin, discolouration, swelling, wheezing or shortness of breath
- aseptic meningitis (stiff neck, headache, feeling or being sick, fever, disorientation) has been reported particularly in patients with lupus (SLE) or other mixed connective tissue disease
- very rarely, Stevens-Johnson syndrome, inflammation or blistering of the skin, mouth or tongue and/or inflammation of the eyes with increased sensitivity to sunlight. These may be severe and be accompanied by feeling generally unwell.

Other side effects
- feeling or being sick, vomiting, diarrhoea, flatulence, constipation, worsening of colitis or Crohn's disease
- less frequently, gastritis (inflammation of the stomach lining)
- very rarely, inflammation of the pancreas (pancreatitis)
- swelling, high blood pressure and heart failure
- fever, weakness, feeling unwell, shortness of breath, abnormal vision, headache, unusual sensations such as burning or tingling in the hands or feet, depression, confusion hallucinations, ringing in the ears (tinnitus), dizziness (including vertigo), tiredness, tremor, sleep difficulties (insomnia), drowsiness.
- anaemia, sore throat, fever, unexpected bleeding.
- yellowing of the skin or whites of the eyes

- increased need to urinate, difficulty passing urine or discolouration of urine
- changes in liver function and changes in the blood can only be detected by blood tests
- inflammation of blood vessels (vasculitis)
- feelings of having rapid, fluttering or pounding heart (palpitations)
- small increased risk of heart attack ("myocardial infarction") or stroke

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 any point of contact of Torrent Pharma available at:
http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting.
By reporting side effects, you can help provide more information on the safety of this Medicine.

9.5 How to store Toldin ER 600
Keep this medicine out of the sight and reach of children.

Store protected from light and moisture, at a temperature not exceeding 30^0C.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last date of that month.

Do not throw away any medicines via wastewater or house hold waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help with the environment.

9.6 Contents of the pack and other information
What Toldin ER 600 tablet contains
The active substance is Etodolac
- The other ingredients are:
  Methocel, Microcrystalline Cellulose, Sodium Lauryl Sulphate, Talcum, Colloidal Silicon Dioxide and Magnesium Stearate.

  What Toldin ER 600 looks like and contents of the pack
  Toldin ER 600 is packed in blister strips of 10 tablets

10. Details of manufacturer
Ravenbhel Healthcare Pvt Ltd.,
16-17, EPIP, SIDCO, Kartholi,
Bari-Brahmana, Jammu-181133

11. Details of permission or licence number with date
JK/01/56 issued on 28.10.2009

12. Date of revision
Oct 2019

MARKETED BY
TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,
Ahmedabad-380 009, INDIA

IN/TOLDIN ER 600 mg/OCT-19/03/PI