Artwork Document Information	Artwork Type [Please Tick /]	Sign / Stamp
Product : T-ZOLTEROL 75MG/100MG [FRONT] SAP No. : Date : 11 September 2025	☐ Unit Box ☑ Leaflet ☐ Aluminium Foil ☐ Generic Box ☐ Outer Box ☐ Fix-A-Form ☐ Sachet ☐ Label ☐ Shipper Carton ☐ Others : _____	

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☑ RA/NPRA Artwork ☐ Recirculation Artwork ☐ Approval Copy Artwork ☐ Clean Copy
☐ Internal Artwork Circulation ☐ Previous Approved Artwork ☐ Draft Artwork
☐ Others : _____

Remarks

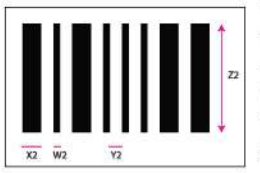
1. Font : Arial Regular (Spacing - 4.8pt / Size - 4.5pt)
2. Dimension : 221mm(w) x 205mm(h)

Colour

Black

Colours shown on this proof are to indicate correct colour separations.

Pharmacode / QR Code / Others Info



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ZOLTEROL™ SR

100mg and 75mg Tablets

Antirheumatic, non-steroidal anti-inflammatory analgesic.

PRODUCT DESCRIPTION
Zolterol SR Tablet 100mg are pale pink, round, film coated tablet, plain on both sides.
Zolterol SR Tablet 75mg are pale pink, triangular tablet, film coated tablet, plain on both sides.

COMPOSITION
Zolterol 100mg SR Tablet - active ingredient: Diclofenac sodium 100mg.
Zolterol 75mg SR Tablet - active ingredient: Diclofenac sodium 75mg.

PHARMACOLOGICAL ACTION
Zolterol SR tablet contains diclofenac sodium, a non-steroidal compound with pronounced antirheumatic, anti-inflammatory, analgesic and antipyretic properties. Inhibition of prostaglandin biosynthesis, which has been demonstrated in experiments, is considered to be fundamental to its mechanism of action. Prostaglandins play an important role in causing inflammation, pain, and fever. Diclofenac sodium in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to the concentrations reached in humans.

In rheumatic diseases, the anti-inflammatory and analgesic properties of diclofenac elicit a clinical response characterized by marked relief from signs and symptoms such as pain at rest, pain on movement, morning stiffness, and swelling of the joints, as well as by an improvement in function.

In post-traumatic and post-operative inflammatory conditions, diclofenac rapidly relieves both spontaneous pain and pain on movement and reduces inflammatory swelling and wound edema.

Zolterol 75 mg and 100 mg sustained-release tablets are particularly suitable for patients in whom a daily dose of 75 mg or 100 mg is To update as brand leader (Voltaren) appropriate to the clinical picture. The possibility of prescribing the medicinal product in a single daily dose considerably simplifies long-term treatment and helps to avoid the possibility of dosage errors. Zolterol 75 mg sustained -release tablets also allow the maximum daily dose of 150 mg to be given in a balanced b.i.d. schedule.

PHARMACOKINETICS
Absorption
Judged by urinary recovery of unchanged diclofenac and its hydroxylated metabolites, the same amount of diclofenac is released and absorbed from diclofenac sustained-release tablets as from gastro-resistant tablets. However, the systemic availability of diclofenac from diclofenac sustained-release tablets is on average about 82% of that achieved with the same dose of diclofenac administered in the form of gastro-resistant tablets (possibly due to release-rate dependent "first-pass" metabolism). As a result of a slower release of the active substance from diclofenac sustained-release tablets, peak concentrations attained are lower than those observed following the administration of gastro-resistant tablets. Mean peak concentrations of 0.5 micrograms/mL or 0.4 micrograms/mL (1.6 or 1.25 micromol/L) are reached on average 4 hours after ingestion of a sustained-release tablet of 100 mg or 75 mg. Food has no clinically relevant influence on the absorption and systemic availability of diclofenac sustained-release tablets. On the other hand, mean plasma concentrations of 13 ng/mL (40 nmol/L) can be recorded at 24 hours (16 hours) after administration of diclofenac sustained-release tablets 100 mg (75 mg). Since about half of diclofenac is metabolized during its first passage through the liver ("first pass" effect), the area under the concentration curve (AUC) following oral or rectal administration is about half that following an equivalent parenteral dose. Trough concentrations are around 22 ng/mL or 25 ng/mL (70 nmol/L or 80 nmol/L) during treatment with diclofenac sustained-release tablets 100 mg once daily or 75 mg twice daily. Pharmacokinetic behaviour does not change after repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

Distribution
99.7% of diclofenac binds to serum proteins, mainly to albumin (99.4%). The apparent volume of distribution calculated is 0.12 to 0.17 L/kg. Diclofenac enters the synovial fluid, where maximum concentrations are measured 2 to 4 hours after peak plasma values have been reached. The apparent half-life for elimination from the synovial fluid is 3 to 6 hours. Two hours after reaching peak plasma levels, concentrations of the active substance are already higher in the synovial fluid than in the plasma, and they remain higher for up to 12 hours.

Biotransformation/metabolism
Biotransformation of diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites (3'-hydroxy-,4'-hydroxy-,5-hydroxy-,4',5-dihydroxy-, and 3'-hydroxy-4'methoxy-diclofenac), most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, but to a much lesser extent than diclofenac.

Elimination
Total systemic clearance of diclofenac from plasma is 263 ± 56 mL/min (mean value ± SD). The terminal half-life in plasma is 1 to 2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1 to 3 hours. One metabolite, 3'-hydroxy-4'-methoxydiclofenac, has a much longer plasma half-life. However, this metabolite is virtually inactive. About 60% of the administered dose is excreted in the urine as the glucuronide conjugate of the intact molecule and as metabolites, most of which are also converted to glucuronide conjugates. Less than 1% is excreted as unchanged substance. The rest of the dose is eliminated as metabolites through the bile in the faeces.

Linearity/non-linearity
The amount absorbed is linearly related to the dose strength

Special populations
Geriatric patients
No relevant age-dependent differences in the drug's absorption, metabolism, or excretion have been observed. However, in a few elderly patients a 15-minute intravenous infusion resulted in 50% higher plasma concentrations than expected from the data on young healthy subjects.

Renal impairment
In patients suffering from renal impairment, no accumulation of the unchanged active substance can be inferred from the single-dose kinetics when applying the usual dosage schedule. At a creatinine clearance of less than 10 mL/min, the calculated steady-state plasma levels of the hydroxy metabolites are about 4 times higher than in normal subjects. However, the metabolites are ultimately cleared through the bile.

Hepatic impairment
In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of diclofenac are the same as in patients without liver disease.

INDICATIONS
Zolterol SR tablet is indicated for the treatment of:
- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism.
- Painful post-traumatic and post-operative inflammation and swelling.
- Primary dysmenorrhoea.

RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION
As general recommendation, the dose should be individually adjusted. Adverse effects may be minimized by using lowest effective dose for the shortest duration necessary to control symptoms (see section WARNINGS and PRECAUTIONS).

Method of administration
Zolterol SR tablet should be swallowed whole with liquid, preferably with meals. Do not crush or chew.

General target population
Adults
The recommended initial daily dose is 100 to 150 mg, administered as 1 tablet of Zolterol SR 100 mg or as 2 tablets of Zolterol SR 75 mg. In milder cases, as well as for long-term therapy, 75 to 100 mg daily is usually sufficient. Where the symptoms are most pronounced during the night or in the morning, Zolterol SR 75 mg and 100 mg should preferably be taken in the evening.

Special populations
Renal impairment
Zolterol SR tablet is contraindicated in patients with renal failure (GFR <15 mL/min/1.73 m2) (see section CONTRAINDICATIONS).
No specific studies have been carried out in patients with renal impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering Zolterol SR tablet to patients with renal impairment (see section WARNINGS AND PRECAUTIONS).

Hepatic impairment
Zolterol SR tablet is contraindicated in patients with hepatic failure (see section CONTRAINDICATIONS).
No specific studies have been carried out in patients with hepatic impairment, therefore, no specific dose adjustment recommendations can be made. Caution is advised when administering Zolterol SR tablet to patients with mild to moderate hepatic impairment (see section WARNINGS AND PRECAUTIONS).

Paediatric patients
Due to the high dosage strength, Zolterol SR tablet is not recommended for children and adolescents below 18 years.

Geriatric patients (65 years of age or above)
No adjustment of the starting dose is generally required for elderly patients. However, caution is indicated on basic medical grounds, especially for frail elderly patients or those with a low body weight (see section WARNINGS AND PRECAUTIONS).

Established cardiovascular disease or significant cardiovascular risk factors
Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidaemia, diabetes mellitus and smoking) should be treated with diclofenac only after careful consideration and only at doses ≤100 mg daily if treated for more than 4 weeks (see section WARNINGS AND PRECAUTIONS).

CONTRAINDICATIONS
Zolterol SR tablet is contraindicated in patients with
- Known hypersensitivity to diclofenac and other NSAIDs or to any of the other excipients.
- Active gastric or intestinal ulcer, bleeding or perforation (see sections WARNINGS AND PRECAUTIONS and SIDE EFFECTS).
- Last trimester of pregnancy (see sectionPREGNANCY AND LACTATION,).
- Hepatic failure.
- Renal failure (GFR <15 mL/min/1.73 m2).
- Severe cardiac failure (see sectionWARNINGS AND PRECAUTIONS).
- Like other non-steroidal anti-inflammatorydrugs (NSAIDs), Zolterol SR tablet is alsocontraindicated in patients in whom the use ofacetylsalicylic acid or other NSAIDs canprecipitate asthma, angioedema, urticaria, oracute rhinitis (i.e., NSAID-inducedcrossreactivity reactions) (see sectionsWARNINGS AND PRECAUTIONS and SIDEEFFECTS).

WARNINGS AND PRECAUTIONS
Gastrointestinal effects
Gastrointestinal bleeding, ulceration or perforation, which can be fatal, have been reported with all NSAIDs, including diclofenac, and may occur at any time during treatment, with or without warning symptoms or a previous history of serious gastrointestinal events. They generally have more serious consequences in the elderly. If gastrointestinal bleeding or ulceration occurs in patients receiving Zolterol SR tablet, the treatment should be discontinued. As with all NSAIDs, including diclofenac, close medical surveillance is imperative and particular caution should be exercised when prescribing Zolterol SR tablet in patients with symptoms indicative of gastrointestinal (GI) disorders or with a history suggestive of gastric or intestinal ulceration, bleeding or perforation (see section SIDE EFFECTS). The risk of GI bleeding is higher with increasing NSAID doses and in patients with a history of ulcer, particularly if complicated with hemorrhage or perforation and in the elderly.

To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with hemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose. Combination therapy with protective agents (e.g., proton pump inhibitors or misoprostol) should be considered for these patients, and also for patients requiring concomitant use of low dose acetylsalicylic acid (ASA), or other drugs likely to increase gastrointestinal risk. Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding). Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants, anti-platelet agents or selective serotonin-reuptake inhibitors (see section INTERACTIONS). Close medical surveillance and caution should also be exercised in patients with ulcerative colitis or Crohn's disease, as their condition may be exacerbated (see section SIDE EFFECTS).

NSAIDs, including diclofenac, may be associated with increased risk of gastro-intestinal anastomotic leak. Close medical surveillance and caution are recommended when using diclofenac after gastro-intestinal surgery.

Cardiovascular effects
Treatment with NSAIDs including diclofenac, particularly at high dose and in long term, may be associated with an increased risk of serious cardiovascular thrombotic events (including myocardial infarction and stroke).

Treatment with diclofenac is generally not recommended in patients with established cardiovascular disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension. If needed, patients with established cardiovascular disease, uncontrolled hypertension, or significant risk factors for cardiovascular disease (e.g. hypertension, hyperlipidemia, diabetes mellitus and smoking) should be treated with diclofenac only after careful consideration and only at doses ≤100 mg daily when treatment continues for more than 4 weeks.

As the cardiovascular risks of diclofenac may increase with dose and duration of exposure, the lowest effective daily dose should be used for the shortest duration possible. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially when treatment continues for more than 4 weeks.

Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g., chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event.

Hematologic effects
During prolonged treatment with Zolterol SR tablet, as with other NSAIDs, monitoring of the blood count is recommended. Like other NSAIDs, diclofenac may temporarily inhibit platelet aggregation. Patients with defects of hemostasis should be carefully monitored.

Respiratory effects (pre-existing asthma)
In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e., nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms), reactions on NSAIDs like asthma exacerbations (so-called intolerance to analgesics / analgesics-asthma), Quincke's edema or urticaria are more frequent than in other patients. Therefore, special caution is recommended in such patients (readiness for emergency). This is applicable as well for patients who are allergic to other substances, e.g., with skin reactions, pruritus or urticaria.

Hepatobiliary effects
Close medical surveillance is required when prescribing Zolterol SR tablet to patients with impaired hepatic function, as their condition may be exacerbated. As with other NSAIDs, including diclofenac, values of one or more liver enzymes may increase. During prolonged treatment with Zolterol SR tablet (e.g., in the form of tablets or suppositories), regular monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g., eosinophilia, rash), Zolterol SR tablet should be discontinued. Hepatitis may occur with use of diclofenac without prodromal symptoms. Caution is called for when using Zolterol SR tablet in patients with hepatic porphyria, since it may trigger an attack.

Skin reactions
Serious skin reactions, 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 NSAIDs, including Zolterol SR tablet (see section SIDE EFFECTS). Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring inthe majority of cases within the first month of treatment. Zolterol SR tablet should be discontinued at the first appearance of skin rash, mucosal lesions or any other sign of hypersensitivity. As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur in rare cases with diclofenac without earlier exposure to the drug.

Renal effects
As fluid retention and edema have been reported in association with NSAID therapy, including diclofenac, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and in those patients with substantial extracellular volume depletion of any cause, e.g., before or after major surgery (see section CONTRAINDICATIONS). Monitoring of renal function is

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Remarks

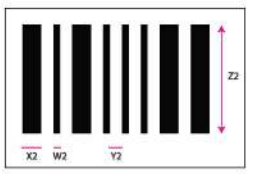
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recommended as a precautionary measure when using Zolterol SR tablet in such cases. Discontinuation of therapy is usually followed by recovery to the pre-treatment state.

Geriatric patients
Caution is indicated in the elderly on basic medical grounds, especially in frail elderly patients or those with a low body weight.

Interactions with NSAIDs
The concomitant use of Zolterol SR tablet with systemic NSAIDs including cyclooxygenase-2 selective inhibitors, should be avoided due to undesirable effects (see section INTERACTIONS WITH OTHER MEDICAMENTS).

Masking signs of infections
Like other NSAIDs, diclofenac may mask the signs and symptoms of infection due to its pharmacodynamic properties.

WARNINGS
RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID
Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms. Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious adverse events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events

Severe cutaneous reactions, including Stevens - Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac sodium. Patients treated with diclofenac sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue diclofenac sodium immediately if rash occurs.

Adverse effects: Dermatological:
Occasional - rashes or skin eruptions Cases of hair loss, bullous eruptions, erythema multiforme, Stevens- Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

DRUG INTERACTIONS
The following interactions include those observed with Zolterol sustained release tablets and/or other pharmaceutical forms of diclofenac.

Observed interactions to be considered
CYP2C9 inhibitors: Caution is recommended when co-prescribing diclofenac with CYP2C9 inhibitors (such as voriconazole), which could result in a significant increase in peak plasma concentrations and exposure to diclofenac.

Lithium: If used concomitantly, diclofenac may raise plasma concentrations of lithium.
Monitoring of the serum lithium level is recommended.

Digoxin: If used concomitantly, diclofenac may raise plasma concentrations of digoxin.
Monitoring of the serum digoxin level is recommended.

Diuretics and antihypertensive agents: Like other NSAIDs, concomitant use of diclofenac with diuretics or antihypertensive agents (e.g.,beta-blockers, angiotensin converting enzyme (ACE) inhibitors) may cause a decrease in their antihypertensive effect. Therefore, the combination should be administered with caution and patients, especially the elderly, should have their blood pressure periodically monitored. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter, particularly for diuretics and ACE inhibitors due to the increased risk of nephrotoxicity (see section WARNINGS AND PRECAUTIONS).

Ciclosporin and tacrolimus: Diclofenac, like other NSAIDs, may increase the nephrotoxicity of ciclosporin and tacrolimus due to the effect on renal prostaglandins. Therefore, it should be given at doses lower than those that would be used in patients not receiving ciclosporin or tacrolimus.

Drugs known to cause hyperkalemia:
Concomitant treatment with potassium-sparing diuretics, ciclosporin, tacrolimus or trimethoprim may be associated with increased serum potassium levels, which should therefore be monitored frequently (see section WARNINGS AND PRECAUTIONS)

Quinolone antibacterials: There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

Anticipated interactions to be considered
Other NSAIDs and corticosteroids:
Concomitant administration of diclofenac and other systemic NSAIDs or corticosteroids may increase the frequency of gastrointestinal undesirable effects (see section WARNINGS AND PRECAUTIONS).

Anticoagulants and anti-platelet agents:
Caution is recommended since concomitant administration could increase the risk of bleeding (see section WARNINGS AND PRECAUTIONS). Although clinical investigations do not appear to indicate that diclofenac affects the action of anticoagulants, there are reports of an increased risk of hemorrhage in patients receiving diclofenac and anticoagulants concomitantly. Close monitoring of such patients is therefore recommended.

Selective serotonin reuptake inhibitors (SSRIs): Concomitant administration of systemic NSAIDs, including diclofenac, and SSRIs may increase the risk of gastrointestinal bleeding (see section WARNINGS AND PRECAUTIONS).

Antidiabetics: Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of both hypoglycemic and hyperglycemic effects necessitating changes in the dosage of the antidiabetic agents during treatment with diclofenac. For this reason, monitoring of the blood glucose level is recommended as a precautionary measure during concomitant therapy.

There have also been isolated reports of metabolic acidosis when diclofenac was coadministered with metformin, especially in patients with pre-existing renal impairment.

Phenytoin: When using phenytoin concomitantly with diclofenac, monitoring of phenytoin plasma concentrations is recommended due to an expected increase in exposure to phenytoin.

Methotrexate: Caution is recommended when NSAIDs, including diclofenac, are administered less than 24 hours before or after treatment with methotrexate, since blood concentrations of methotrexate may rise and the toxicity of this substance be increased.

CYP2C9 inducers: Caution is recommended when co-prescribing diclofenac with CYP2C9 inducers (such as rifampicin), which could result in a significant decrease in plasma concentration and exposure to diclofenac.

Pregnancy
There are insufficient data on the use of diclofenac in pregnant women. Some epidemiological studies suggest an increased risk of miscarriage after use of a prostaglandin synthesis inhibitor (such as NSAIDs) in early pregnancy, however the overall data are inconclusive. Diclofenac has been shown to cross the placental barrier in humans. Use of NSAIDs, including diclofenac, can cause uterine inertia, premature closure of the fetal ductus arteriosus and fetal renal impairment leading to oligohydramnios. Because of these risks, Zolterol SR tablet should not be used during the first two trimesters of pregnancy unless the expected benefits to the mother outweigh the risks to the fetus. In addition, Zolterol SR tablet should not be used during the third trimester of pregnancy (see section CONTRAINDICATIONS).

Lactation
Like other NSAIDs, diclofenac passes into the breast milk in small amounts. Therefore, Zolterol SR should not be administered during breast-feeding in order to avoid undesirable effects in the infant

SIDE EFFECTS/ADVERSE REACTIONS
Adverse drug reactions from clinical trials and/or spontaneous or literature cases are listed by MedDRA system organ class. The corresponding frequency category for each adverse drug reaction is based on the following convention (CIOMS III): very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

Blood and lymphatic system disorders
Very rare: Thrombocytopenia, leukopenia, anemia (including hemolytic and aplastic anemia), agranulocytosis.

Immune system disorders
Rare: Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock).
Very rare: Angioedema (including face edema).

Psychiatric disorders
Very rare: Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder.

Nervous system disorders
Common: Headache, dizziness.
Rare: Somnolence.
Very rare: Paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident.

Eye disorders
Very rare: Visual impairment, blurred vision, diplopia.

Ear and labyrinth disorders
Common: Vertigo.
Very rare: Tinnitus, impaired hearing.

Cardiac disorders
Uncommon*: Myocardial infarction, cardiac failure, palpitations, chest pain
*The frequency reflects data from long-term treatment with high dose (150mg/day)
Kounis syndrome: Frequency "not known"

Vascular disorders
Very rare: Hypertension, vasculitis.

Respiratory, thoracic and mediastinal disorders
Rare: Asthma (including dyspnea).
Very rare: Pneumonitis.

Gastrointestinal disorders
Common: Nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite.
Rare: Gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis, or perforation, which may lead to peritonitis).
Very rare: Colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis.

Hepatobiliary disorders
Common: Transaminases increased.
Rare: Hepatitis, jaundice, liver disorder.
Very rare: Fulminant hepatitis, hepatic necrosis, hepatic failure

Skin and subcutaneous tissue disorders
Common: Rash.
Rare: Urticaria.
Very rare: Bullous dermatitis, eczema, erythema, erythema multiforme, StevensJohnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensitivity reaction, purpura, HenochSchoenlein purpura, pruritus.

Renal and urinary disorders
Very rare: Acute kidney injury (acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis.

General disorders and administration site conditions
Rare: Edema.

Description of selected adverse drug reactions
Arteriothrombotic events
Meta-analysis and pharmacoepidemiological data point towards an increased risk of arteriothrombotic events (for example myocardial infarction) associated with the use of diclofenac, particularly at a high dose (150 mg daily) and during long-term treatment (see section WARNINGS AND PRECAUTIONS).

Visual effects
Visual disturbances such as visual impairment, blurred vision or diplopia appear to be NSAID class effects and are usually reversible on discontinuation. A likely mechanism for the visual disturbances is the inhibition of prostaglandin synthesis and other related compounds that alter the regulation of retinal blood flow resulting in potential changes in vision. If such symptoms occur during diclofenac treatment, an ophthalmological examination may be considered to exclude other causes

SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTE (S)
Symptoms
There is no typical clinical picture resulting from diclofenac overdosage. Overdosage can cause symptoms such as vomiting, gastrointestinal hemorrhage, diarrhea, dizziness, tinnitus or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.

Therapeutic measures
Management of acute poisoning with NSAIDs, including diclofenac, essentially consists of supportive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression. Special measures such as forced diuresis, dialysis, or hemoperfusion are probably of no help in eliminating NSAIDs, including diclofenac, due to the high protein binding and extensive metabolism. Activated charcoal may be considered after ingestion of a potentially toxic overdose, and gastric decontamination (e.g.,vomiting, gastric lavage) after ingestion of a potentially life-threatening overdose.

PHARMACEUTICAL INFORMATION
Storage conditions
Store below 30°C in a cool dry place.
Protect from moisture and heat.
Keep out of reach of children.
Jauhi ubat-ubatan daripada kanak-kanak.

Shelf Life
Please refer to outer package.

Pack size / package
Blister packs of 100's tablets for both Zolterol SR 75mg and 100mg tablet.

PRODUCT REGISTRATION HOLDER :
DUOPHARMA MARKETING SDN. BHD.
Lot No. 2, 4, 6, 8 & 10, Jalan P/7, Section 13, Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor, Malaysia.

MANUFACTURER :
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Lot No. 2 & 4, Jalan P/7, Section 13,Bangi Industrial Estate,
43650 Bandar Baru Bangi, Selangor, Malaysia.

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September 2025

DUOPHARMA