

# New Zealand Datasheet

## Name of Medicine

### VOLTAREN<sup>®</sup> RAPID 25

Diclofenac potassium tablets 25 mg

Diclofenac potassium liquid capsules 25 mg

## Presentation

Each VOLTAREN RAPID 25 tablet contains 25 mg of diclofenac potassium. The tablets are pale red, round, biconvex sugar-coated with "CG" on one side and "DD" on the other. The diameter is about 7.7 mm with a thickness of about 5.0 mm.

Each VOLTAREN RAPID 25 liquid capsule contains 25 mg of diclofenac potassium. The capsules are oval translucent and yellow in colour.

## Uses

### Actions

#### Pharmacotherapeutic group

Anti-inflammatory and anti-rheumatic products, non-steroids, acetic acid derivatives and related substances (ATC code M01A B05).

#### Pharmacodynamic effects

VOLTAREN RAPID 25 contains the potassium salt of diclofenac, a non-steroidal compound with pronounced analgesic, anti-inflammatory, and antipyretic properties.

VOLTAREN RAPID 25 has a rapid onset of action which makes them particularly suitable for the treatment of acute painful and inflammatory conditions. Inhibition of prostaglandin biosynthesis, which has been demonstrated in experiments, is considered to be fundamental to its mechanism of action. Prostaglandins play a major role in causing inflammation, pain, and fever.

VOLTAREN RAPID 25 has been found to exert a pronounced analgesic effect in moderate and severe pain. In the presence of inflammation, e.g. due to trauma or following surgical interventions, it rapidly relieves both spontaneous pain and pain on movement and diminishes inflammatory swelling and wound oedema. Clinical studies have also revealed that in primary dysmenorrhoea the active substance is capable of relieving the pain and reducing the extent of bleeding. In migraine attacks VOLTAREN RAPID 25 has been shown to be effective in relieving the headache and in improving the accompanying symptoms nausea and vomiting.

## Pharmacokinetics

### Absorption

Diclofenac is rapidly and completely absorbed. Following ingestion in the fasted state of one 25 mg liquid capsule, mean peak plasma concentration of 1,125 ng/mL is reached after approximately 25 minutes (median T<sub>max</sub>). The amount absorbed is in linear proportion to the size of the dose.

When VOLTAREN RAPID tablets were taken with food, the rate of absorption of diclofenac was reduced. As food effects are expected to be similar for all immediate release formulations of diclofenac potassium, on this basis, for maximum efficacy, VOLTAREN RAPID tablets or liquid caps should not be taken directly with or immediately after meals.

Since about half of diclofenac is metabolized during its first passage through the liver ("first pass" effect), the area under the concentration curve (AUC) is about half as large following oral or rectal administration as it is following a parenteral dose of equal size.

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 0.12-0.17 L/kg.

Diclofenac enters the synovial fluid, where maximum concentrations are measured 2-4 hours after peak plasma values have been reached. The apparent half-life for elimination from the synovial fluid is 3-6 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

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  $263 \pm 56$  mL/min (mean value  $\pm$  SD). The terminal half-life in plasma is 1-2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1-3 hours. One metabolite, 3'-hydroxy-4'-methoxy-diclofenac, 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.

### Characteristics in patients

No relevant age-dependent differences in the drug's absorption, metabolism, or excretion have been observed.

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.

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**

Short-term treatment in the following acute conditions:

- post-traumatic pain, inflammation and swelling, e.g. due to sprains;
- post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery;
- painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis;
- migraine attacks;
- painful syndromes of the vertebral column;
- non-articular rheumatism;
- as an adjuvant in severe painful inflammatory infections of the ear, nose, or throat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.

## **Dosage and Administration**

### **Adults**

After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

Following an initial loading dose of 50 mg, 25-50 mg is to be taken every eight hours if necessary. The maximum daily dose is 150 mg.

### **MIGRAINE**

An initial loading dose of 50 mg, then if necessary a further 25-50 mg after 2 hours. The maximum daily dose is 150 mg.

The tablets or soft capsules should be swallowed whole with liquid, preferably before meals.

### **Children**

Children over 14 years of age: up to 75 mg daily in divided doses.

The dosage strength is such that VOLTAREN RAPID 25 is not recommended for use in children 14 years of age or below.

## **Contraindications**

- Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other non-steroidal anti-inflammatory drugs such as ibuprofen (see Warnings and Precautions – pre-existing asthma)
- Active gastric or intestinal ulcer, bleeding or perforation (see Warnings and Precautions – gastrointestinal effects)
- Last trimester of pregnancy (see Warnings and Precautions – use in pregnancy).
- Severe hepatic, renal or cardiac failure (see Warnings and Precautions).

## **Warnings and Precautions**

### **Warnings**

VOLTAREN RAPID 25 liquid caps contain sorbitol and therefore are not recommended for patients with rare hereditary problems of fructose intolerance.

#### **Cardiovascular Thrombotic Events**

Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events, including myocardial infarction and stroke, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk factors may also be at greater risk. To minimise the potential risk of an adverse cardiovascular event in patients taking an NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration (see Dosage and Administration).

There is no consistent evidence that the concurrent use of aspirin mitigates the possible increased risk of serious cardiovascular thrombotic events associated with NSAID use.

#### **Hypertension**

NSAIDs may lead to the onset of new hypertension or worsening of pre-existing hypertension and patients taking anti-hypertensives with NSAIDs may have an impaired anti-hypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.

#### **Heart failure**

Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.

### Gastrointestinal Events

As with all NSAIDs, including diclofenac, close medical surveillance is imperative and particular caution should be exercised when prescribing NSAIDs, including diclofenac, in patients with symptoms indicative of gastrointestinal (GI) disorders or with a history suggestive of gastrointestinal ulceration, bleeding or perforation (see Adverse Effects).

Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occur in approximately 1% of patients treated for 3-6 months and in about 2-4% patients treated for one year. The risk of GI bleeding is higher with increasing NSAID doses and in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation and in the elderly.

Gastric or duodenal ulceration, perforation or gastrointestinal bleeding, which can be fatal, have been reported in patients receiving diclofenac potassium tablets. Studies to date have not identified any subset of patients who are not at risk of developing these problems.

Caution is advised in patients with risk factors for gastrointestinal events who may be at greater risk of developing serious gastrointestinal events, e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism.

When gastrointestinal bleeding or ulcerations occur in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patients about the signs and symptoms of serious gastrointestinal toxicity.

The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal events.

To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly, the treatment should be initiated and maintained at the lowest effective dose. Gastrointestinal bleeding, ulceration and perforation in general have more serious consequences in the elderly. They can occur at any time during treatment with or without warning symptoms or a previous history. In instances where gastrointestinal bleeding or ulcerations occur in patients receiving VOLTAREN RAPID, the drug should be withdrawn immediately. Physicians should warn patients about the signs and symptoms of serious gastrointestinal toxicity and what steps to take if they occur.

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 medicinal products containing low-dose acetylsalicylic acid (ASA)/aspirin, 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 Warnings and Precautions – interactions with other drugs).

Close medical surveillance should also be exercised in patients with ulcerative colitis or Crohn's disease, as well as in patients suffering from pre-existing dyshaemopoiesis or disorders of blood coagulation, as their condition may be exacerbated (see Adverse Effects).

### Severe 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 VOLTAREN RAPID 25 (see Adverse Effects). These serious adverse events are idiosyncratic and are independent of dose or duration of use. 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. Patients should be advised of the signs

and symptoms of serious skin reactions and to consult their doctor at the first appearance of skin rash, mucosal lesion or any other sign of hypersensitivity, and VOLTAREN RAPID 25 should be discontinued.

#### Pre-existing asthma

In patients with asthma, seasonal allergic rhinitis, swelling of nasal mucosa (i.e. nasal polypus), chronic obstructive pulmonary disease or chronic infection of the respiratory tract (especially if linked to allergic rhinitis-like symptoms), reactions to NSAIDs such as asthma exacerbations (so-called intolerance to analgesics / analgesics-asthma), Quincke's oedema or urticaria are more frequent than in other patients. Special precaution is recommended in such patients (readiness for emergency). This is also applicable to patients who are allergic to other substances, e.g. with skin reactions, pruritus or urticaria.

#### Hepatic effects

Close medical surveillance is required when prescribing diclofenac to patients with impaired hepatic function, as their condition may be exacerbated (see Contraindications).

As with other NSAIDs, including diclofenac, elevations of one or more liver enzymes may occur during VOLTAREN RAPID therapy. These laboratory abnormalities may progress, remain unchanged, or revert to normal despite continued therapy. Severe hepatotoxicity may develop with use of diclofenac without prodromal symptoms.

If, contrary to its recommended use for short term treatment, VOLTAREN RAPID is administered for a more prolonged period, monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs and/or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash), diclofenac should be discontinued.

Physicians should inform patients of the warning signs and symptoms of hepatotoxicity (e.g. nausea, fatigue, lethargy, pruritus, jaundice, abdominal tenderness in the right upper quadrant and "flu-like" symptoms) and the appropriate action to take should these signs and symptoms appear. Caution is called for when using VOLTAREN RAPID 25 in patients with hepatic porphyria, since VOLTAREN RAPID 25 may trigger an attack.

#### Renal effects

As a class, NSAIDs have been associated with renal papillary necrosis and other renal pathology during long-term administration in animals.

Fluid retention and oedema have been reported in association with NSAID therapy, including diclofenac. Owing to the importance of prostaglandins for maintaining renal blood flow, particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, in the elderly, in patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and in those patients with extracellular volume depletion from any cause, e.g. in the peri- or post-operative phase of major surgical operations (see Contraindications).

Monitoring of renal function is recommended as a precautionary measure when using VOLTAREN RAPID 25 in such cases. Discontinuation of therapy is normally followed by a return to the pretreatment state.

#### Infection

Like other NSAIDs, VOLTAREN RAPID may mask the usual signs and symptoms of infection due to its pharmacodynamic properties.

#### Haematological effects

Use of VOLTAREN RAPID is recommended only for a few days. If, however, VOLTAREN RAPID is used for a more prolonged period, monitoring of the blood count is recommended.

Like other NSAIDs, VOLTAREN RAPID 25 may temporarily inhibit platelet aggregation. Patients with haemostatic disorders should be carefully monitored.

#### Hypersensitivity

As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions have been reported with diclofenac. These reactions can occur without earlier exposure to the drug.

#### Mutagenicity, carcinogenicity, and reproduction toxicity studies:

Diclofenac showed no mutagenic, carcinogenic, or teratogenic effects in the studies conducted, despite the induction of maternal and foetal toxicity.

### **Use in the elderly**

In patients of advanced age, caution is indicated on basic medical grounds. In particular it is recommended that the lowest effective dosage be used in frail elderly patients or those with low body weight. Treatment with VOLTAREN RAPID 25 in the elderly usually proves necessary only for a few days.

### **Use in Pregnancy**

NSAIDs inhibit prostaglandin synthesis and, when given during the latter part of pregnancy, may cause closure of the foetal ductus arteriosus, foetal renal impairment, inhibition of platelet aggregation, and delay labour and birth.

The use of diclofenac in pregnant women has not been studied and safety in pregnancy has not been established. Therefore, VOLTAREN RAPID should not be used in pregnant women during the first two trimesters or in women who are likely to become pregnant unless the potential benefit to the mother outweighs the risk to the foetus. As with other NSAIDs, use of diclofenac during the third trimester of pregnancy is contraindicated owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus (see Contraindications).

Animal studies have not shown any directly or indirectly harmful effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

### **Use in Lactation**

Following oral doses of 50 mg administered every 8 hours, the active substance passes into the breast milk. As with other drugs that are excreted in milk, VOLTAREN RAPID is not recommended for use in nursing women.

### **Effects on fertility**

As with other NSAIDs, the use of diclofenac 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 diclofenac should be considered.

### **Use in children**

VOLTAREN RAPID 25 is not recommended for use in children 14 years of age and under as safety and efficacy in this age group have not been established. It should be noted that there are no data concerning any pharmacokinetic parameters related to the use of diclofenac in children. A pharmacokinetic study in adults indicated a doubling of the peak concentration and a halving of the time to the peak concentration (see – Pharmacokinetics).

### **Effects on Ability to Drive and Use Machines**

Usually there is no effect at the recommended low-dose and short duration of treatment. However patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking diclofenac should refrain from driving or operating machines.

### **Adverse Effects**

Whilst not all the reactions listed have been reported specifically with VOLTAREN RAPID 25, similarities between the NSAIDs as a group require them to be considered possible.

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: common ( $\geq 1/100$ ,  $< 1/10$ ); uncommon ( $\geq 1/1,000$ ,  $< 1/100$ ); rare ( $\geq 1/10,000$ ,  $< 1/1,000$ ); very rare ( $< 1/10,000$ ), including isolated reports.

The following undesirable effects include those reported with long term use of higher doses of diclofenac.

Table 1.

<b>Blood and lymphatic system disorders</b>	
Very rare:	Thrombocytopenia, leukopenia, anaemia (including haemolytic anaemia and aplastic anaemia), agranulocytosis.
<b>Immune system disorders</b>	
Rare:	Hypersensitivity, anaphylactic and anaphylactoid reaction (including hypotension and shock).
Very rare:	Angioneurotic oedema (including face oedema).
<b>Psychiatric disorders</b>	
Very rare:	Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder.
<b>Nervous system disorders</b>	
Common:	Headache, dizziness.
Rare:	Somnolence.
Very rare:	Paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident.
<b>Eye disorders</b>	
Very rare:	Visual disturbance, vision blurred, diplopia.
<b>Ear and labyrinth disorders</b>	
Common:	Vertigo.
Very rare:	Tinnitus, hearing impaired.
<b>Cardiac disorders</b>	
Very rare:	Palpitations, chest pain, cardiac failure, myocardial infarction.
<b>Vascular disorders</b>	
Very rare:	Hypertension, vasculitis.
<b>Respiratory, thoracic and mediastinal disorders</b>	
Rare:	Asthma (including dyspnoea).
Very rare:	Pneumonitis.
<b>Gastrointestinal disorders</b>	
Common:	Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia.
Rare:	Gastritis, gastrointestinal haemorrhage, Haematemesis, diarrhoea hemorrhagic, melaena, gastrointestinal ulcer (with or without bleeding or perforation).
Very rare:	Colitis, (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis.
<b>Hepatobiliary disorders</b>	
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 eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus.

#### **Renal and urinary disorders**

Very rare:	Acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis.
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#### **General disorders and administration site conditions**

Rare:	Oedema.
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## **Interactions**

The following interactions include those observed with other pharmaceutical forms of diclofenac at high doses.

**Lithium:** When given together with preparations containing lithium or digoxin, diclofenac may raise their plasma concentrations and these concentrations should be monitored during treatment with diclofenac.

**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. When NSAIDs, including diclofenac are combined with diuretics, ACE inhibitors or angiotensin II receptor antagonists, the risk of worsening of renal function, including possible acute renal failure (which is usually reversible) may be increased in some patients, especially when renal function is compromised (e.g. dehydrated or elderly patients). Patients should be adequately hydrated and monitoring of renal function is recommended after initiation of concomitant therapy and periodically thereafter. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, thus making it necessary to monitor the latter (see Warnings and Precautions – renal effects).

**Other NSAIDs and corticosteroids:** The concomitant use of diclofenac and systemic NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects. Concomitant administration of diclofenac and other systemic NSAIDs or corticosteroids may increase the frequency of gastrointestinal undesirable effects. Concurrent treatment with aspirin lowers the plasma concentration, peak plasma levels and AUC values of diclofenac. The use of both drugs concurrently is not recommended.

**Anticoagulants and anti-platelet agents:** Caution is recommended since concomitant administration could increase the risk of bleeding (see Warnings and Precautions – gastrointestinal effects). The concurrent use of NSAIDs and warfarin has been associated with severe, sometimes fatal, haemorrhage. The exact mechanism of the interaction between NSAIDs and warfarin is unknown, but may involve enhanced bleeding from NSAID-induced gastrointestinal ulceration or an additive effect of anticoagulation by warfarin and inhibition of platelet function by NSAIDs. Diclofenac should be used with caution in combination with warfarin and such patients should be closely monitored.

**Selective serotonin reuptake inhibitors (SSRIs):** Concomitant administration of systemic NSAIDs, including diclofenac, and SSRIs may increase the risk of gastrointestinal bleeding (see Warnings and Precautions – gastrointestinal effects).

**Antidiabetics:** Clinical studies have shown that VOLTAREN RAPID 25 can be given together with oral antidiabetic agents without influencing their clinical effect. However, isolated cases have been reported of both hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of hypoglycaemic agents during treatment with VOLTAREN RAPID 25. For this reason, monitoring of the blood glucose level is recommended as a precautionary measure during concomitant therapy.

**Methotrexate:** Caution is called for if NSAIDs 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.

**Cyclosporin:** The effects of NSAIDs on renal prostaglandins may increase the nephrotoxicity of cyclosporin. Therefore, it should be given at doses lower than those that would be used in patients not receiving cyclosporin.

**Glucocorticoids:** The addition of glucocorticoids to NSAIDs, though sometimes necessary for therapeutic reasons, may aggravate gastrointestinal side effects.

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

Concomitant administration of voriconazole with diclofenac may increase plasma diclofenac levels.

## Overdosage

Management of acute poisoning with NSAIDs consists essentially of supportive and symptomatic measures. There is no typical clinical picture associated with overdosage of diclofenac. Overdose can cause symptoms such as vomiting, gastrointestinal haemorrhage, diarrhoea, dizziness, tinnitus or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.

The following therapeutic measures should be taken in cases of overdosage:

Absorption should be prevented as soon as possible after the overdosage by treatment with activated charcoal.

Supportive and symptomatic treatments are indicated for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression. Haematological and biochemical parameters, and the presence or absence of blood in the stools, should be monitored.

Specific measures such as forced diuresis, dialysis, or haemoperfusion are unlikely to be helpful in eliminating NSAIDs, including diclofenac, because of their high protein-binding rate and extensive metabolism.

Contact the Poisons Information Centre on 0800 764 766 for advice on management.

## Pharmaceutical Precautions

Protect from moisture and heat (store below 30°C).  
Medicines should be kept out of the reach of children.

## Medicine Classification

Pharmacist Only Medicine

## **Package Quantities**

Blister packs of 10, 20 and 30 tablets.

Blister packs of 10, 20 and 30 soft capsules.

## **Further Information**

### **Instructions for use/handling**

The tablets or capsules should be swallowed whole with liquid, preferably before meals.

### **Excipients**

Tablet core

Silica aerogel, calcium phosphate, magnesium stearate, pregelatinized maize starch, polyvidone, sodium carboxymethyl starch.

Tablet coat

Microcrystalline cellulose, iron oxide, titanium dioxide, macrogol 8000; polyvidone, sucrose, talc.

Soft capsules content

Polyethylene glycol 600, glycerol (E422).

Soft capsule shell

Gelatin, glycerol (E422), sorbitol liquid partially dehydrated (containing sorbitan and mannitol), quinoline yellow (E104). Trace amounts of medium chain triglycerides and phospholipid based surfactant (Phosal 53 MCT) are also present.

Each VOLTAREN RAPID 25 liquid capsule or tablet contains 2.9 mg of potassium.

### **Incompatibilities**

Not applicable

### **Name and Address**

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### **Date of Preparation**

27 May 2010