**RUFENAC 50 TABLETS**

(Diclofenac Tablets BP)

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**RUFENAC-50** Tablets

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| **Ingredients** | **Quantity per tablet** |
|---|---|
| Diclofenac Sodium BP | 50.0 mg |
| Calcium Hydrogen Phosphate BP | 42.751 mg |
| Sodium Starch Glycolate BP | 15.0 mg |
| *Maize Starch BP | 53.027 mg |
| Sodium Benzoate BP | 0.40 mg |
| Magnesium Stearate BP | 1.50 mg |
| Cellacefate BP | 15.70 mg |
| Purified Talc BP | 0.86 mg |
| Titanium Dioxide BP | 0.68 mg |
| Sunset Yellow Supra IH | 0.17 mg |
| Purified water BP | 49.1 µl |
| **Acetone BP | 92.10 mg |
| **Methanol BP | 30.75 µl |
| **Castor Oil BP | 0.86 mg |
| **Diethyl Phthalate BP | 1.00 µl |

* 8% extra added to compensate loss on drying.
** Does not appear in final product.

**Note:** BP: British Pharmacopoeia Edition 2015
IH: In-House Specification

## 3. PHARMACEUTICAL FORM

Tablets (Solid Oral)

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Rufenac-50 is an anti-inflamm atory drug: As a long term treatm ent in certain inflammatory rheumatisms, certa in polyarthr itis an d arthr itis, a s a short ter m treatm ent in inf lammatory growths of localised rheumatism, gout and sciatica.

### 4.2 Posology and method of administration

Route of Administration: Oral

Adults: 1 tablet of 50 mg**.** 3 times a day (150mg/day).

As a support treatment: 1 tablet of 50 mg. 2 times a day (100mg/day).

It is advisable to take the tablets before meals.

## 4.3 Contraindications

Rufenac-50 must not be used in the following cases: An known allergy to dicl ofenac or a related drug, ulcers of the stom ach or duodenum in the past, serious disorders of th e liver, serious dysfunctioning of the kidneys.

## 4.4 Special warnings and precautions for use

Must not be given to children less than one year old. Those driving vehicles and using machines must be careful the treatment can rarely cau se dizzin ess. As it is necessary to adapt the treatment, the doctor preparing the prescription must be infor med in case of: heart, liver or kidney problems, any old allergy or attack of asthm a at the tim e of t aking aspiri n or another anti-inflamm atory drug, contraception by wearing a loop, pregnancy & nursing.

## 4.5 Interaction with other medicinal products and other forms of interaction

Serious interactions have been re ported after the use of high dose m ethotrexate with diclofenac. Blood concentrations of lithium are increased when diclofenac is administered concomitantly.

Aspirin: Protein binding of dicl ofenac m ay be reduced; in addition, the risk of gastric erosion and bleeding may be increased. Cyclosporine: May incr ease nephrotoxicity. Digoxi n: May increase digoxin serum concentrations. Furosem ide and Thiazide Diuretics: May inhi bit diuretic and antihypertensive effects. Lith ium: May decrea se lith ium Cl. Methotre xate: May inc rease m ethotrexate leve ls. W arfarin: May increase risk of gastric erosion.

## 4.6 Pregnancy and lactation

The use of diclofenac in pregnant wom en has not been studied. T hese ag ents (NSAIDs) inhib it prostaglandin synthesis and, when gi ven during the latter pa rt of pregnancy, m ay cause closure of the foetal ductus arteriosus, foetal rena l impairment, inhibition of platelet aggregation, and delay labour and birth. Therefore, diclofenac should not be used during the f irst two tr imesters of pregnancy unless the potential benefit to the mother outweighs th e risk to th e foetus. As with other NSAIDs, use during the third trim ester of pregnancy is c ontraindicated owing to the possib ility of uterine iner tia and/o r premature closure of the ductus arteriosus. Like othe r NSAIDs, diclofenac passes in to the breast milk in small amounts. Therefore, diclofenac should not be administered during breast feeding in order to avoid adverse effects in the infant.

## 4.7 Effects on ability to drive and use machines

None.

## 4.8 Undesirable effects

Stomach ache, vom iting, skin eruption, itching, asthm atic attack, fever, tonsillit is, or other signs of infection. In certain rare cases, th ere can be a possibility of haem orrhage in the digestive tract (blood through the mouth and in stools). Stop the treatment at once and inform your doctor.

## 4.9 Overdose

There is no specific antidote. In cases of overdosage, absorption should be prevented as soon as possible by the induction of vomting, gastric lavage or treatment with activated charcoal. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastro intestinal irritatio n and resp iratory dep ression. Measu res to accelerate elim ination (forced diuresis, hemoperfusion, dialysis) m ay be c onsidered, but m ay be of lim ited use because of the high protein-binding and extensive metabolism.

## 5. PHARMACOLOGICAL PROPERTIES

ATC Code: M01AB05

## 5.1 Pharmacodynamic properties

Diclofenac sodium is a non-steroidal com pound, a phenylacetic acid derivative, with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the bios ynthesis and release of prostaglandins, which are known to be im plicated in the pathogenesis of inflammation, pain and fever. Rufenac 50 Tablets are enteric-coated so that absorption occurs in the gastrointestinal tract to give peak plasma concentrations approximately 2 hours after ingestion.

## 5.2 Pharmacokinetic properties

A comparison of diclofenac pharmac okinetics in young volunteers with rheumatoid patients showed a reduction in the peak plasm a concentration in the latter group but no significa nt change in A UC or elimination half-life.

| | | |
|---|---|---|
| Oral absorption | : | 90% |
| Pre-systemic metabolism | : | 40% |
| Plasma half-life | : | 1-2 h |
| Volume of distribution | : | 0.121 $kg^{-1}$ |
| Plasma protein binding | : | 99.5% |

## 5.3 Preclinical safety data

No additional data of relevance.

## 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Calcium Hydrogen Phosphate BP, Sodium Starch Glycolate BP, Maize Starch BP, Sodium Benzoate BP, Magnesium Stearate BP, Cellacefate BP, Purified Talc BP, Titanium Dioxide BP, Castor oil BP and Diethyl Phthalate BP.

## 6.2 Incompatibilities

None.

## 6.3 Shelf life

36 months.

## 6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

## 6.5 Nature and contents of container

Aluminium / PVC film blister.

Rufenac-50 is available in a blister pack of 10 tablets. 25 such filled blisters are packed in a printed carton along with one leaflet.

## 6.6 Special precautions for disposal and other handling

None.

## 7. MARKETING AUTHORISATION HOLDER

SHALINA HEALTHCARE DMCC

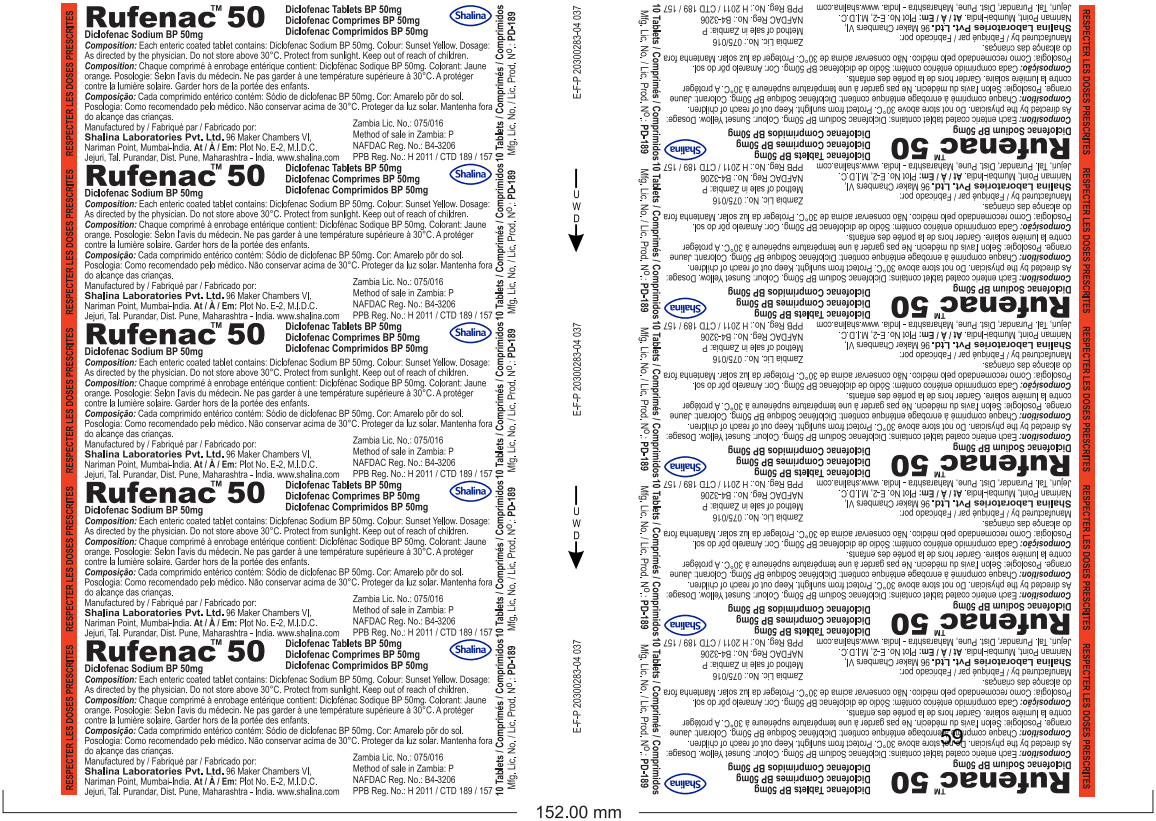
30th Floor, Almas Towers,

Jumeirah Lakes Towers Dubai-UAE.

## 8. MARKETING AUTHORISATION IN OTHER COUNTRIES

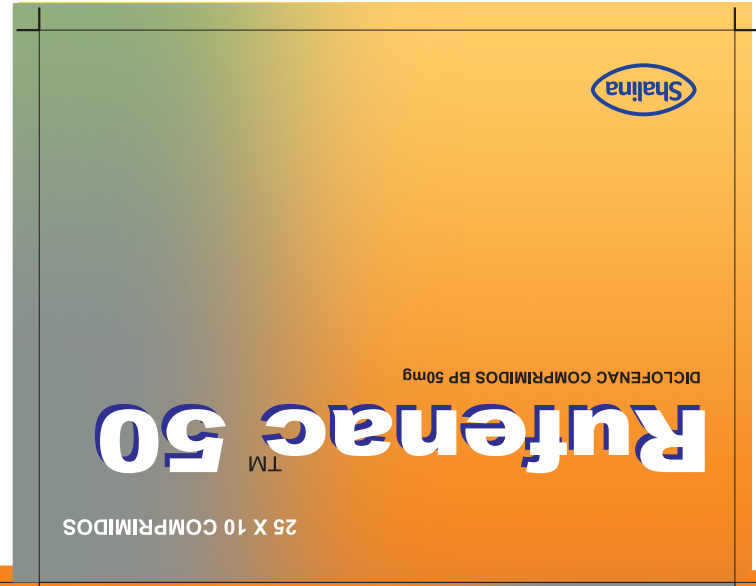
Product is registered in Democratic Republic of Congo, Central African Republic, Nigeria, Zambia and Kenya.

### 1.3.2 **Labelling (outer & inner labels)** - Enclosed


RESPECTER LES DOSES PRESCRITES
Rufenac™ 50
Diclofenac Sodium BP 50mg
Diclofenac Tablets BP 50mg
Diclofenac Comprimes BP 50mg
Diclofenac Comprimidos BP 50mg
Shalina
10 Tablets / Comprimés / Comprimidos
Mfg. Lic. No./ Lic. Prod. N°: PD-189
Composition: Each enteric coated tablet contains: Diclofenac Sodium BP 50mg. Colour: Sunset Yellow.
Dosage: As directed by the physician. Do not store above 30°C. Protect from sunlight. Keep out of reach of children.
Composition: Chaque comprimé a enrobage entérique contient: Diclofénac Sodique BP 50mg. Colorant: Jaune orange.
Posologie: Selon l'avis du médecin. Ne pas garder à une température supérieure à 30°C. A protéger contre la lumière solaire.
Garder hors de la portée des enfants.
Composição: Cada comprimido entérico contém: Sódio de diclofenac BP 50mg. Cor: Amarelo pôr do sol.
Posologia: Como recomendado pelo médico. Não conservar acima de 30°C. Proteger da luz solar.
Mantenha fora do alcance das crianças.
Manufactured by / Fabriqué par / Fabricado por:
Shalina Laboratories Pvt. Ltd., 96 Maker Chambers VI, Nariman Point, Mumbai-India.
At / A / Em: Plot No. E-2, M.I.D.C. Jejuri, Tal. Purandar, Dist. Pune, Maharashtra - India. www.shalina.com
Zambia Lic. No.: 075/016
Method of sale in Zambia: P
NAFDAC Reg. No.: B4-3206
PPB Reg. No.: H 2011 / CTD 189 / 157
E-F-P 20300283-04 037

152.00 mm

50




RESPECTER LES DOSES PRESCRITES
UNIQUEMENT SUR ORDONNANCE - LISTE I

**Rufenac™ 50**
Diclofenac Sodium BP 50mg

**Composition:** Each enteric coated tablet contains: Diclofenac Sodium BP 50mg. Colour: Sunset Yellow. Dosage: As directed by the physician. Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

**Composition:** Chaque comprimé à enrobage entérique contient: Diclofénac Sodique BP 50mg. Colorant: Jaune orange. Posologie: Selon l'avis du médecin. Ne pas garder à une température supérieure à 30°C. A protéger contre la lumière solaire. Garder hors de la portée des enfants.

**Composição:** Cada comprimido entérico contém: Sódio de diclofenac BP 50mg. Cor: Amarelo pôr do Sol. Posologia: Como recomendado pelo médico. Não conservar acima de 30°C. Proteger da luz solar. Mantenha fora do alcançe das crianças.

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Manufactured by / Fabriqué par / Fabricado por:
**SHALINA LABORATORIES PVT. LTD.**
96, Maker Chambers VI, Nariman Point, Mumbai - India.
**At / À / Em:** Plot No. E - 2, M.I.D.C. Jejuri, Tal. Purandar, Dist. Pune, Maharashtra - India. www.shalina.com

Zambia Lic. No.: 075/016
Method of sale in Zambia: P
NAFDAC Reg. No.: B4-3206

25 X 10 COMPRIMÉS

# Rufenac™ 50

DICLOFENAC COMPRIMÉS BP 50mg

Shalina

E / F / P 20200878-04 037

**Rufenac™ 50**
Diclofenac Sodium BP 50mg

Mfg. Lic. No. / Lic. Prod. N°.: PD-189
Batch No. /
Lote N°:
Mfg. Date /
Data Fab.:
Exp. Date /
Data Exp.:

25 X 10 TABLETS

# Rufenac™ 50

DICLOFENAC TABLETS BP 50mg

60

Shalina

### 1.3.3 Package Insert (also known as patient information PIL) - Enclosed

# Rufenac™ 50

## Diclofenac Tablets BP 50mg

**Composition:** Each enteric coated tablet contains: Diclofenac Sodium BP 50mg. Colour: Sunset Yellow.

Excipients: Sodium Starch Glycolate BP, Maize Starch BP, Sodium Benzoate BP, Calcium Hydrogen Phosphate BP, Purified Talc BP, Magnesium Stearate BP, Titanium Dioxide BP, Castor oil BP, Diethyl Phthalate BP and Cellacefate BP.

**Pharmacological Category: Rufenac 50** is a NSAID (Non steroidal anti-inflammatory drug).

**Pharmacological Action:** Diclofenac sodium is a non-steroidal compound, a phenylacetic acid derivative, with analgesic, antipyretic and anti-inflammatory effects. Diclofenac sodium inhibits the biosynthesis and release of prostaglandins, which are known to be implicated in the pathogenesis of inflammation, pain and fever. **Rufenac 50** Tablets are enteric-coated so that absorption occurs in the gastrointestinal tract to give peak plasma concentrations approximately 2 hours after ingestion.

**Therapeutic Indications: Rufenac 50** is a an anti-inflammatory drug: As a long term treatment in certain inflammatory rheumatisms, certain polyarthritis and arthritis, as a short term treatment in inflammatory growths of localised rheumatism, gout and sciatica.

**Contraindication: Rufenac 50** must not be used in the following cases: an known allergy to diclofenac or a related drug, ulcers of the stomach or duodenum in the past, serious disorders of the liver, serious dysfunctioning of the kidneys.

**Dosage and method of administration:** Adults: 1 tablet of 50mg
3 times a day (150mg./day). As a support treatment: 1 tablet of 50mg
2 times a day (100mg/day). It is advisable to take the tablets before meals.

**Pharmacokinetic Properties:** A comparison of diclofenac pharmacokinetics in young volunteers with rheumatoid patients showed a reduction in the peak plasma concentration in the latter group but no significant change in AUC or elimination half-life.

| | |
|---|---|
| Oral absorption | 90 % |
| Presystemic metabolism | 40 % |
| Plasma half-life | 1-2 h |
| Volume of distribution | 0.121. kg-1 |
| Plasma protein binding | 99.5 % |

**Adverse Reaction:** Stomach ache, vomiting, skin eruption, itching, asthmatic attack, fever, tonsillitis, or other signs of infection. In certain rare cases, there can be a possibility of haemorrhage in the digestive tract (blood through the mouth and in stools). Stop the treatment at once and inform your doctor.

**Warnings & precautions for use in special populations:** Must not be given to children less than one year old. Those driving vehicles and using machines must be careful the treatment can rarely cause dizziness. As it is necessary to adapt the treatment, the doctor preparing the prescription must be informed in case of : heart, liver or kidney problems, any old allergy or attack of asthma at the time of taking aspirin or another anti-inflammatory drug, contraception by wearing a loop, pregnancy & nursing.

**Usage in Pregnancy & Lactation:** The use of diclofenac in pregnant women has not been studied. These agents (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. Therefore, diclofenac should not be used during the first two trimesters of pregnancy unless the potential benefit to the mother outweighs the risk to the foetus. As with other NSAIDs, use during the third trimester of pregnancy is contraindicated owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus. Like other NSAIDs, diclofenac passes into the breast milk in small amounts. Therefore, diclofenac should not be administered during breast feeding in order to avoid adverse effects in the infant.

**Effects on ability to drive and operate machinery:** Not applicable.

**Drug Interactions:** Serious interactions have been reported after the use of high dose methotrexate with diclofenac. Blood concentrations of lithium are increased when Rufenac-50 is administered concomitantly. Aspirin: Protein binding of diclofenac may be reduced; in addition, the risk of gastric erosion and bleeding may be increased. CYCLOSPORINE: May increase nephrotoxicity. DIGOXIN: May increase digoxin serum concentrations. FUROSEMIDE AND THIAZIDE DIURETICS: May inhibit diuretic and antihypertensive effects. LITHIUM: May decrease lithium Cl. METHOTREXATE: May increase methotrexate levels. WARFARIN: May increase risk of gastric erosion.

**Symptoms of over dosage & its treatment:** There is no specific antidote. In cases of overdosage, absorption should be prevented as soon as possible by the induction of vomiting, gastric lavage or treatment with activated charcoal. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal irritation and respiratory depression. Measures to accelerate elimination (forced diuresis, hemoperfusion, dialysis) may be considered, but may be of limited use because of the high protein-binding and extensive metabolism.

**Storage Condition:** Do not store above 30°C. Protect from sunlight. Keep out of reach of children.

**Presentation:** Blister of 10 Tablets, Pack of 25 x 10 Tablets & 10 x 10 Tablets.

Pack of 25 x 10 Tablets
Zambia Lic. No.: 075/016
Method of sale in Zambia: P
NAFDAC Reg. No.: B4-3206

Pack of 25 x 10 Tablets & 10 x 10 Tablets
PPB Reg. No.: H 2011 / CTD 189 / 157

Shalina
Manufactured by / Fabriqué par / Fabricado por:
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96, Maker Chambers VI, Nariman Point, Mumbai - India.
**At / À / Em:**Plot No. E-2, M.I.D.C. Jejuri, Tal. Purandar, Dist. Pune, Maharashtra - India. www.shalina.com

E / F / P 20600385-03 037

# Rufenac™ 50

## Diclofénac Comprimés BP 50mg

**Composition:** Chaque comprimé à enrobage entérique contient: Diclofénac Sodium BP 50mg. Couleur: Jaune orange.

Excipients: Glycolate de sodium amidonné BP, amidon de maïs BP, Benzoate de sodium BP, Hydrogéno Phosphate de Calcium BP, Talc purifié BP, Stéarate de magnésium BP, Dioxyde de titane BP, Huile de ricin BP, Diéthyl Phatalate BP et Cefacellate BP.

**Groupe pharmacologique: Rufenac 50** est un AINS (non stéroïdiens anti-inflammatoire).

**Action pharmacologique:** le diclofénac sodique est un composé non stéroïdien, un dérivé de l'acide phényl acétique, avec des propriétés anti pyrétiques et anti inflammatoires. Le diclofénac sodique inhibe la synthèse des prostaglandines, reconnues comme responsables des phénomènes d'inflammations, de douleurs et de fièvres. Les comprimés de **Rufenac 50** sont enrobés, par conséquent l'absorption intervient dans la partie gastro-intestinale pour donner le pic plasmatique environ 2 heures après l'ingestion.

**Indications thérapeutiques: Rufenac 50** est un médicament anti-inflammatoire préconise: En traitement de longue durée dans certains rhumatismes inflammatoires, certaines polyarthrites et l'arthrose, en traitement de courte durée dans les poussées inflammatoires des rhumatismes localisés, les poussées douloureuses d'arthrose, la gouttee et les sciatiques.

**Contre-indications: Rufenac 50** ne doit pas être utilisé dans les cas suivants: Allergie connue au diclofénac ou à un médicament apparenté, ulcère de l'estomac ou du duodénum en évolution, maladie grave du foie, maladie grave des reins.

**Posologie et mode d'administration:** Adultes: 1 comprimé, 50mg
3 fois par jour (150mg/jour). En traitement d'entretien: 1 comprimé, (50mg)
2 fois par jour (100mg/jour). En cas de crise aigue, il est conseillé de prendre les comprimés avant le repas.

**Propriétés pharmacocinétiques:** Une comparaison de la pharmacocinétique du diclofénac chez des jeunes volontaires souffrant des rhumatismes a montré une réduction du pic plasmatique chez le dernier groupe mais pas de modification significative de l'AUC ou de la demi-vie d'élimination.

| | |
|---|---|
| Absorption orale | 90 % |
| Métabolisme pré systémique | 40 % |
| Demi-vie plasmatique | 1-2 h |
| Volume de distribution | 0,121 kg/l |
| Liaison aux protéines plasmatiques | 99.5 % |

**Réactions adverses:** Des douleurs de l'estomac, des vomissements, une éruption sur la peau, des démangeaisons, une crise d'asthme, de la fièvre, une angine ou d'autres signes d'infection. Dans certains cas rares, il est possible que survienne une hémorragie digestive (rejet de sang par la bouche ou dans les selles). Il faut immédiatement arrêter le traitement et avertir votre médecin.

**Avertissement & Précautions d'emploi chez des sujets particuliers:** Ne doit pas être donné aux enfants de moins d'un an. L'attention est attirée chez les conducteurs de véhicules et les utilisateurs de machines, le traitement pouvant entrainer rarement des étourdissements. En raison de la nécessité d'adapter le traitement, il est important de prévenir le médecin qui rédige l'ordonnance en cas: De maladie du coeur, du foie ou du rein, d'allergie ancienne ou de crise d' asthme lors de la prise d'aspirine ou d'un autre anti-inflammatoire, de contraception par port de stérilet, de grossesse, d'allaitement.

**Utilisation pendant la grossesse et l'allaitement:** L'usage du diclofenac chez les femmes enceintes n'a pas été étudié. Ces composés(AINS) inhibent la synthèse de la prostaglandine et, une fois administrés pendant le dernièr trimestre de la grossesse, ils peuvent causer la fermeture prématurée du canal artériel, l'insuffisance rénale chez le foetus, l'inhibition de l'aggrégation plaquettaire et retarder le travail et l'accouchement. Donc, diclofenac ne devrait pas être utilisé pendant les deux premiers trimestres de la grossesse à moins que l'avantage potentiel chez la mère dépasse le risque chez le foetus. Comme avec les autres AINS, l'emploi durant le troisième trimestre de la grossesse est contre-indiqué par suite de la possibilité de l'inertie utérine et/ou de la fermeture prématurée du canal artériel. Comme pour les autres AINS, Diclofénac passe dans le lait maternel. Par mesure de précaution, il convient d'éviter de les administrer chez la femme qui allaite.

**Effets sur la capacité de conduire et de surveiller les machines:** Non applicable.

**Interactions médicamenteuses:** Inhibiteurs de l'enzyme de conversion: L'effet antihypertenseur des Inhibiteurs de l'enzyme de conversion peut être réduit. Aspirine: la liaison aux protéines par le diclofenac peut être réduit; En plus, le risque de perforation ou de l'hémorragie gastrique peut être augmenté. CYCLOSPORINE: augmentation de la nephrotoxicité. DIGOXINE: augmentation des concentrations sériques de la digoxine. Furosemide et les diurétiques thiazidiques: inhibition des effets diurétiques et antihypertensifs. LITHIUM: diminution des taux sériques du lithium. METHOTREXATE: Augmentation des concentrations de methotrexate. WARFARINE: augmentation du risque de perforation gastrique.

**Symptômes de surdosage et traitement:** Il n'y a pas d'antidote spécifique. En cas de surdosage, l'absorption doit etre évitée dès que possible par l'induction de vomissements, le lavage gastrique ou le traitement avec le charbon actif. Le traitement symptomatique doit etre envisagé dans des complications telles que l'hypotension, l'insuffisance rénale, les convulsions, l'irritation gastro-intestinale et la dépression respiratoire. Les mesures pour accélérer l'élimination (la diurèse forcée, l'hemoperfusion, la dialyse), peuvent être utilisées, mais peuvent être d'utilisation limitée à cause de sa forte liaison aux protéines et de son métabolisme très vaste.

**Conditions de Conservation:** Ne pas garder à une température supérieure à 30°C. A protéger contre la lumière solaire. Garder hors de la portée des enfants.

**Presentation:** Plaquette thermoformée de 10 comprimés, Boîte de 25 x 10 Comprimés et 10 x 10 Comprimés.

# Rufenac™ 50

## Comprimidos de Diclofenac BP 50mg

**Composição:** Cada comprimido entérico revestido contém: Sódio de Diclofenac BP 50mg. Cor: Amarelo pôr do sol.

Excipientes: Carboximetilamido Sodica BP, Amido de milho BP, Benzoato de Sódio BP, Hidrogênio fosfato de cálcio BP, Talco purificado BP, Estearato de Magnésio BP, Dióxido de Titânio BP, Óleo de ricio BP, Dietilftalato BP e Cefacellata BP.

**Categória Farmacologica: Rufenac50** é um NSAID (uma droga anti-inflamatória não esteroide).

**Acção Farmacologica:** O diclofenaco sódico é um composto não esteroide, um derivado ácido feniloacético, com efeitos analgésico, antipirético a anti-inflamtório. O diclofenaco sódico inibe a biossíntese e a liberação das prostaglandinas, que estão envolvidas na patogênese da inflamação, da dor e da febre. As tabletas de **Rufenac 50** tem um vestido entérico de forma que a absorção ocorre no trato gastrointestinal para dar concentrações plasmáticas máximas aproximadamente 2 horas depois da ingestão.

**Indicações terapêuticas:** O **Rufenac 50** é uma droga anti-inflamatória: Como um tratamento de longo prazo nos alguns reumatismos inflamatórios, nas certas poliartrite e artrite, como um tratamento de curto prazo nos tumores inflamatórios do reumatismo localizado, da gota e da ciática.

**Contra-Indicações:** Não recomenda-se tomar o **Rufenac 50** nos seguintes casos: uma alergia conhecida ao diclofenaco ou à uma droga associada, úlceras do estômago ou do duodeno no passado, doenças sérias do fígado, disfunção séria dos rins.

**Posologie e modo de administração:** Adultos: 1 tableta de 50mg 3 vezes ao dia (150mg/dia). Como tratamento de apoio: 1 tableta de 50 mg 2 vezes ao dia (100mg/dia). É apropriado tomar as tabletas antes das refeições. Uma comparação da farmacocinética dO diclofenaco nos voluntáraios jovens com os enfermos reumatóides mostro uma redução na concentração plasmática máxima no último grupo mais nenhum câmbio significativo no AUC ou na meia-vida da eliminação.

**Propriedades Farmacocinéticas:**
Uma comparação do diclofenaco farmacocinética em voluntários jovens com pacientes com artrite reumatóide mostrou uma redução na concentração plasmática de pico no último grupo, mas nenhuma mudança significativa na AUC e meia-vida.

| | |
|---|---|
| Absorção oral | 90% |
| Metabolismo presistémico | 40% |
| Meia-vida plasmática | 1 às 2 horas |
| Volume da distribuição | 0,121 kg-1 |
| Ligação às proteínas plasmáticas | 99,5 % |

**Reacções adversas:** Dor do estômago, vômito, erupção cutânea, coceira, ataque asmático, febre, amigdalite ou outros signos da infecções. No certos casos raros, pode haber uma possibilidade de hemorragia no trato digestivo (o sangue a través da boca e das fezes). Recomenda-se parar o tratamento imediatamente e avisar o seu médico.

**Atenção e Precauções para uso em populações especiais:** Não recomenda-se administrar aos crianças menos de um ano. Recomenda-se que aqueles que conduzem veículos e que sirvam-sedas máquinas são cautelosos, o tratamento raramente pose produzir vertigem. Já que é necessário adaptar o tratamento, recomenda-se avisar ao médico que prepara a receita médica em caso: dos problemas cardíacos, hepáticos ou renais, qualquera velha alergia ou ataque de asma quando está tomando a aspirina ou qualquera outra droga anti-inflamatória, contracepão usando o laço, a gravidez e a amamentação.

**Uso na Gravidez e lactação:** O uso do diclofenaco nas mulheres grávidas não foi estudado. Estes agentes (NSAID) iniben a síntese das prostaglandinas e, quando estão administrados durante a segunda parte da gravidez, eles podem produzir o fechamento do ducto arterial fetal, a insuficiência renal fetal, a inibição da agregação da plaqueta, e retardar o parto e o nascimento. Por essa razão, não recomenda-se usar o diclofenaco durante os dois primeiros quartos da gravidez a menos que o benefício possível à mãe é mais importante que o risco ao feto. Como com ous outros NSAID, o uso durante o terceiro quarto da gravidez está contra-indicado devido à possibilidada inércia uterina e/ou o fechamento prematuro do ducto arterial. Como os outros NSAID, o diclofenaco atravessa no leite materno en pequenas quantidades. Por essa razão, não recomenda-se administrar o diclofenaco durante a amamentação a fim de evitar os efeitos adversos no bebê.

**Efeitos sobre a capacidade de dirigir e operar máquinas:** Não aplicável.

**Interações medicamentosas:** As sérias interações foram observadas depois do uso da dose elevada do metotrexato com o diclofenaco. As concentrações do lítio no sangue aumentam quando o Rufenac-50 está administrado no mesmo tempo. Aspirina: A ligação às proteínas do diclofenaco pode ser reduzida; além disso, o risco da erosão gástrica e da hemorragia pode aumentar. CICLOSPORINA: Pode aumentar a nefrotoxicidade. DIGOXINA: Pode aumentar as concentrações séricas da digoxina. FUROSEMIDA E DIURÉTICOS TIAZÍDICOS: Podem inibir os efeitos diuréticos e antihipertensos. LÍTIO: Pode reduzir o Cl do lítio. METOTREXATO: Pode aumentar os níveis do metotrexato. WARFARINA: Pode aumentar o risco da erosão gástrica.

**Sintomas de sobredosagem e seu tratamento:** Não há nenhum antídoto específico. Nos casos duma dosage excessiva, recomenda-se evitar a absorção o mais cedo possível pela indução do vômito, da lavagem gástrica ou dum tratamento com o carbono ativado. Recomenda-se dar um tratamento de apoio e sintomático para as complicações tão como a hipotensão, a insuficiência renal, as convulsões, a irritação gastrointestinal e a depressão respiratória. É possível considerer as medidas para acelerar a eliminação (a diurese forçada, hemoperfusão, a diálise), mas podem ser do uso restrito por causa da alta ligação às proteínas e do metabolismo extensivo.

**Armazenamento condicional:** Não conservar acima de 30°C. Proteger da luz solar. Mantenha fora do alcance das crianças.

**Apresetação:** Envasado blister de 10comprimidos, Embalagem de 25 x 10 Comprimidos e 10 x 10 Comprimidos.