1.3.1 Summary of product characteristics

Attached Below

National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

BABADOL TABLET
(Diclofenac Sodium BP 50mg + Paracetamol BP 325 mg Tablet)

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BABADOL TABLET
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1. **NAME OF THE MEDICINAL PRODUCT:**

BABADOL TABLET
(Diclofenac Sodium 50mg & Paracetamol 325mg Tablet BP)

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION:**

Each Uncoated Tablet contains:
Diclofenac Sodium BP……50mg
Paracetamol BP..... 325mg
Excipients..... q.s

3. **PHARMACEUTICAL FORM:**

Uncoated Tablet

4. **Clinical particulars :**

THERAPEUTIC INDICATION:
It is indicated for relief of mild to moderate pain, fever also in case of common cold, headache, upper respiratory tract infections & rheumatic originated pain.

Paracetamol is mild analgesic and antipyretic it is recommended for headaches, include migrains and tension headache, backache, rheumatic and muscle pain, nerve pain, toothache and for relieving the fever, aches and pains of colds and flu.

Diclofenac is in a group of drugs called nonsteroidal anti-inflammatory drugs (NSAIDs). It works by reducing hormones that cause inflammation and pain in the body. relieves pain and reduces inflammation (swelling). It is used to treat headaches, muscle aches, dental pain, and athletic injuries. It is commonly used to treat the pain, swelling and stiffness associated with arthritis. Diclofenac is used commonly to treat mild to moderate post-operative or post-traumatic pain, particularly when inflammation is also present, and is effective against menstrual pain

4.2 Posology and method of administration:

Take this medicine in the dose and duration as advised by your doctor. Swallow it as a whole. Do not chew, crush or break it. Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP is to be taken with food. Route ofadministration: Oral

4.3 Contraindications:

It should not be used in

Hypersensitivity against diclofenac & paracetamol.

History of allergic reactions (bronchospasm, shock, rhinitis, urticaria) following the use of Aspirin or another NSAID.

Third-trimester pregnancy.

Active stomach and/or duodenal ulceration or gastrointestinal bleeding.

Inflammative intestinal disorders such as Crohn's disease or ulcerative colitis.

Severe insufficiency of the heart (NYHA III/IV).

Recently, a warning has been issued by FDA not to use to treat patients recovering from heart surgery.

Severe liver insufficiency (Child-Pugh Class C).

Severe renal insufficiency (creatinine clearance <30 ml/min).

4.4 Special warnings and precautions for use:

Special Warning and Precautions for use:

Paracetamol

Skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by drug fever and mucosal lesions. The use of paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

Diclofenac is contra-indicated in aspirin allergy, severe inflammation of the bowel, stomach ulceration and the last third of pregnancy. Reported possible side effects include - stomach pain/upset; bleeding from the stomach, headache, dizziness and rash. Rarely, it has been reported as causing abnormalities of the general blood picture, kidney and liver function; and ulceration of the stomach.

Carcinogenesis, mutagenesis, Teratogenicity:

Although the combination of Diclofenac & paracetamol does cross the placenta the occasional use of therapeutic doses in healthy women does not seem to be associated with an increased risk of malformation and has not been proved to be teratogenic. There seems to be the same degree of renal and hepatotoxicity in the baby as in the mother, so large doses of paracetamol that cause severe maternal toxicity have been associated with foetal kidney and liver damage. There is structural damage (i.e. affecting organ formation) in a 1st trimester exposure and functional damage (i.e. affecting organ maturation and/or function) in 2nd and 3rd trimester exposures. There is also an association with foetal anaemia and neonatal jaundice if the overdose is taken near term.

Drug interaction:

You may need to adjust your usual dose of anticoagulants (eg warfarin) if you take paracetamol regularly. Check with your anticoagulation clinic. Otherwise there are no serious interactions between paracetamol and other drugs.

Serious interactions have been reported after the use of high dose methotrexate with diclofenac. Blood concentrations of lithium are increased when diclofenac is administered concommitantly.

OVERDOSE:

Overdose symptoms may include nausea, vomiting, stomach pain, drowsiness, black or bloody stools, coughing up blood, shallow breathing, and fainting.

Acute paracetamol overdose is defined as an ingestion of a toxic amount of paracetamol occurring within a period of 8 hours or less. A number of steps in the management of such an overdose are important to achieve an optimal clinical outcome. This section outlines basic steps in managing acute paracetamol overdose, consistent with FDA-approved labeling of acetylcysteine.

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

Interactions:

Alcohol: UNSAFE

It is unsafe to consume alcohol with Diclofenac Sodium & Paracetamol 50mg/325mg Tablet Bp .

Kidney: CAUTION

Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP should be used with caution in patients with kidney disease. Dose adjustment of Diclofenac Sodium & Paracetamol 50mg/532mg Tablet BP may be needed. Pleaseconsult your doctor.

Liver: CAUTION

Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP should be used with caution in patients with liver disease. Dose adjustment of Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP may be needed. Pleaseconsult your doctor.

However, the use of Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP is not recommended in patientswith severe liver disease and active liver disease.

4.6 Fertility, pregnancy and lactation:

Fertility & Pregnancy: Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP is unsafe to use during pregnancy as there is definite evidence of risk to the developing baby. However, the doctor may rarely prescribe it in some life-threatening situations if the benefits are more than the potential risks. Please consultyour doctor.

Lactation: Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP is probably safe to use during breastfeeding. Limited human data suggests that the drug does not represent any significant risk to the baby.

4.7 Effects on ability to drive and use machines:

Diclofenac Sodium & Paracetamol 50mg/325mg BP Tablet may cause side effects which could affect your ability to drive.

Diclofenac Sodium & Paracetamol 50mg/325mg Tablet BP may cause headaches, blurred vision, dizziness ordrowsiness in some patients. This may affect your ability to drive.

4.8 Undesirable effects

Side-Effects And Special Precautions:

Nausea, Vomiting, Stomach pain/epigastric pain, Heartburn, Diarrhea, Loss of appetite.

5. Pharmacological properties:

5.1 Pharmacodynamic properties:

Diclofenac is an acetic acid nonsteroidal antiinflammatory drug (NSAID) with analgesic and antipyretic properties. Diclofenac is used to treat pain, dysmenorrhea, ocular inflammation, osteoarthritis, rheumatoid arthritis, ankylosing spondylitis, and actinic keratosis.

Acetaminophen (USAN) or Paracetamol (INN) is a widely used analgesic and antipyretic drug that is used for the relief of fever, headaches, and other minor aches and pains. It is a major ingredient in numerous cold and flu medications and many prescription analgesics. It is extremely safe in standard doses, but because of its wide availability, deliberate or accidental overdoses are not uncommon. Acetaminophen, unlike other common analgesics such as aspirin and ibuprofen, has no anti-inflammatory properties or effects on platelet function, and it is not a member of the class of drugs known as non-steroidal anti-inflammatory drugs or NSAIDs. At therapeutic doses acetaminophen does not irritate the lining of the stomach nor affect blood coagulation, kidney function, or the fetal ductus arteriosus (as NSAIDs can). Like NSAIDs and unlike opioid analgesics, acetaminophen does not cause euphoria or alter mood in any way. Acetaminophen and NSAIDs have the benefit of being completely free of problems with addiction, dependence, tolerance and withdrawal. Acetaminophen is used on its own or in combination with pseudoephedrine, dextromethorphan, chlorpheniramine, diphenhydramine, doxylamine, codeine, hydrocodone, or oxycodone.

5.2 Pharmacokinetic properties:

Diclofenac is a NSAID (NSAID). Paracetamol is an analgesic and antipyretic. When used together, the actions of paracetamol set in earlier and provides pain relief before the effects of diclofenac Na set in.

5.3 Preclinical safety data:

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 Pharmaceutical particulars

6.1 List of excipients;

Sr No	Ingredient	Specification
1	Maize starch	IP
2	Maize starch*****	IP
3	Maize starch	IP
4	PVPK 30	IP
5	Methyl paraben	IP
6	Propyl paraben	IP
7	Talcum	IP
8	Sodium starch glycolate	IP
9	Magnesium sterate	IP
10	Colloidal silicon dioxide	IP

6.2 Incompatibilities: Not applicable.

6.3 Shelf life: 36 Months

6.4 Nature and contents of container: 10 X 1 X 10 Tablets

Blister pack of 10 tablets and such 10 blisters pack in carton along with leaflet.

6.5 Special precautions for disposal and other handling:
Store below 25°C. Protect from light andmoisture. Keep out of reach of children.

6.6 Applicant/manufacturer:

MANUFACTURED BY:
WINTECH PHARMACEUTICAL PVT. LTD.
Plot No. 45-46, STICE, Musalgoan, Sinner,
422112 (Dist-Nashik), Maharashtra, India

APPLICANT:
PATRICKLINGO PHARMACEUTICALS LIMITED
13, Obianwu Street, Onitsha, Nigeria