IBUPROFEN

Dolan® FP 40 mg/mL Suspension (Oral Drops)
Dolan® FP 100 mg/5 mL Suspension
Dolan® FP FORTE 200 mg/5 mL Suspension

Nonsteroidal Anti-inflammatory Drug
Non-Selective COX Inhibitor (Propionic acid derivative)

FORMULATIONS

Each mL suspension (oral drops) contains:
Ibuprofen..... 40 mg

Each 5 mL (1 teaspoonful) suspension contains:
Ibuprofen..... 100 or 200 mg

PRODUCT DESCRIPTIONS

Ibuprofen (Dolan® FP) 40 mg / mL Suspension (Oral Drops), Ibuprofen (Dolan® FP) 100 mg / 5 mL Suspension, and **Ibuprofen (Dolan® FP Forte) 200 mg / 5 mL Suspension** are orange-colored and orange-flavored suspensions using the TasteRite® Technology. TasteRite® technology is a unique tastemasking system developed specifically for liquid dosage forms. This technology significantly reduces the bitterness of the medicine so that children taste the flavor and not the medicine.

WHAT IS IN THE MEDICINE?

These products contain ibuprofen which belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). Like other NSAIDs, ibuprofen works by changing the body's chemical response to pain, swelling and fever resulting in relief of symptoms of inflammation (e.g., swelling, redness) and relief of pain and/or fever.

STRENGTH OF THE MEDICINE

See Formulation.

WHAT IS THIS MEDICINE USED FOR?

For Ibuprofen 40 mg/mL Suspension (Oral Drops)

- For the relief of mild to moderate aches and pains due to:
  - Dental pain including teething pain, toothache
  - Muscular aches or soft tissue injuries including sprains and strains
  - Headache, common cold, flu, or sore throat
- For the relief of other types of pain such as earache, or pain after vaccination or surgery
- For the relief of inflammation from juvenile rheumatoid arthritis
- For fever reduction

For Ibuprofen 100 mg/5 mL and 200 mg/5 mL Suspension

- For the relief of mild to moderate aches and pains due to:
  - Dental pain including teething pain, toothache
  - Headache including migraine, neuralgia (painful disorder of the nerves)
  - Muscular aches including sprains and strains, minor arthritis pain, backache (including low back pain)
  - Common cold, flu, or sore throat
  - Menstrual cramps (dysmenorrhea)
- For the relief of other types of pain such as earache, or pain after vaccination or surgery
- For the relief of inflammation from arthritis, non-serious arthritic conditions, and juvenile rheumatoid arthritis
- For fever reduction

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Like other NSAIDs, the lowest effective dose should be used for the shortest possible time. After observing the response to initial therapy with this product, the dose and frequency should be adjusted to suit individual patient needs.

This medicine is given orally and may be taken with food or milk if stomach upset occurs.

Ibuprofen Drops and Suspension:

Recommended oral dose in children: 5 to 10 mg/kg body weight per dose given every 6 to 8 hours, or, as directed by a doctor.

Age Group	Ibuprofen (Dolan® FP) 40 mg/mL Suspension (Oral Drops)	Ibuprofen (Dolan® FP) 100 mg/5mL Suspension	Ibuprofen (Dolan® FP Forte) 200 mg/5mL Suspension
	Dose given every 6 to 8 hours as needed for pain and/or fever, or, as directed by a doctor.		
Infants			
0 - 2 months	0.5 to 1 mL	–	–
3 - 5 months	1 to 1.5 mL	–	–
6 - 12 months	1.5 to 2 mL	–	–
Children			
1 - 2 years	2 to 2.5 mL	5 mL (1 teaspoonful)	2.5 mL (1/2 teaspoonful)
3 - 6 years	–	5 to 10 mL (1 to 2 teaspoonsful)	2.5 to 5 mL (1/2 to 1 teaspoonful)
7 - 12 years	–	10 mL (2 teaspoonsful)	5 mL (1 teaspoonful)

- Shake well before using.
- Do not give more than directed.
- Do not give more than 4 doses in 24 hours.
- Do not give for longer than 3 days, unless directed by a doctor.

For patients with juvenile rheumatoid arthritis: The usual recommended dose is 7.5 to 12.5 mg/kg body weight per dose given every 6 hours. Consultation with a doctor is strongly recommended for patients with this condition.

WHEN SHOULD YOU NOT USE THIS MEDICINE?

Do not take this medicine if you or your child has or are:

- Allergic to ibuprofen, aspirin or any other NSAID, or to other ingredients in the product
- Currently taking aspirin or other NSAIDs
- Bronchospasm (constriction of air passages of the lungs), angioedema (rapid swelling that occurs in the tissue just below the surface of the skin), nasal polyps or allergic-type reactions after taking aspirin or other NSAIDs
- Suffering from stomach ulcers, bleeding or other stomach problems such as inflammatory bowel disease
- Severe heart or liver disease
- Severe kidney disease (creatinine clearance less than 30 mL/min)
- Conditions involving an increased tendency for active bleeding
- Dehydrated (significant fluid loss) due to vomiting, diarrhea or lack of fluids
- Systemic Lupus Erythematosus (SLE)
- Dengue fever, since NSAIDs may increase the risk of bleeding
- To undergo heart surgery (right before or after)

UNDESIRABLE EFFECTS

Undesirable effects from the use of ibuprofen are rare, but they may occur. Tell your doctor if you experience any undesirable effect.

The most frequently reported undesirable effects (1 to 10%) of ibuprofen include constipation, decreased appetite, diarrhea, dizziness, dyspepsia, ear infection (otitis media), fever, fluid retention, fullness of the gastrointestinal tract (bloating or flatulence), headache, heartburn, indigestion, itching, mouth ulcers (stomatitis), nausea, nervousness, rash, ringing in the ears (tinnitus), sore throat (pharyngitis), stomach cramps or pain, swelling, vertigo, and vomiting.

Less common undesirable effects (<1% of patients) include:

Blood: Bleeding episodes (e.g., nose bleed, heavy menstrual bleeding), blood does not clot properly, decrease in hemoglobin and hematocrit, low platelet count, low red or white blood cell count (i.e., agranulocytosis, aplastic anemia, hemolytic anemia, eosinophilia, granulocytopenia, leukopenia, neutropenia, pancytopenia)

Allergic Reactions: Autoimmune disorders (e.g., SLE, Henoch–Schönlein purpura), constriction of air passages of the lungs, dry mouth, gingival ulceration, hives, itching, rapid swelling beneath the skin (angioedema), serum sickness, stuffy nose (rhinitis), swelling of the face, tongue and voice box, syndrome of abdominal pain, fever, chills, nausea and vomiting, wheezing or difficulty in breathing, whole-body allergic reaction (anaphylaxis), worsening of asthma

Metabolism and Nutrition: Benign enlargement of the male breasts, increased acid in blood and body tissues, low blood sugar, low sodium in the blood, menstrual delay

Psychiatric: Anxiety, confusion, depression, drowsiness, hallucination, insomnia

Nervous System: Dream abnormalities, inflammation of the brain lining (aseptic meningitis; symptoms include stiff neck, headache, feeling or being sick, fever or feeling disoriented), loss of sensation (paresthesia), muscle spasm, tingling of hands and feet

Special Senses: Blurred and/or decreased visual sharpness (amblyopia), cataracts, decreased hearing, depressed vision in the visual field (scotoma) and/or changes in color vision, double vision (diplopia), impaired hearing, inflammation of the optic nerve, inflammation or infection of the membrane lining the eyelids (conjunctivitis), visual disturbance

Cardiovascular: Cerebrovascular accident (stroke), chest pain, fluid retention, heart failure, increased blood pressure, irregular heartbeat, low blood pressure, palpitations, swelling of tissues usually in the lower limbs (edema)

Stomach/Gut: Inflammation of the stomach lining or pancreas, passing black or bloody stools, stomach ulceration and/or bleeding, temporary burning sensation in the mouth or throat, vomiting with blood (or liquid with what looks like coffee grounds), worsening inflammation of the intestine or colon (colitis, Crohn's disease)

Liver: Abnormal liver function tests, inflammation of the liver (hepatitis), liver disorders especially with long-term treatment, liver failure, yellowing of the skin or whites of the eyes (jaundice)

Skin: Blisters, hives, loss of hair, sensitivity to light or the sun; symptoms of serious allergies (e.g., Stevens-Johnson Syndrome, toxic epidermal necrolysis, and erythema multiforme) which include multiple skin lesions, itch, fever, and joint pains

Kidneys: Acute pain on the side or back, blood in the urine, decreased creatinine clearance, excess serum proteins or urea in the urine, frequent urination, inflammation of the bladder (cystitis), kidney damage, kidney failure, swelling of the ankles

Body as a Whole: Fatigue, general ill feeling (malaise), mood swings (emotional lability), tiredness

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE USING THIS MEDICINE?

Aspirin: Ibuprofen may interfere with the anti-platelet activity of aspirin, thus limiting aspirin's cardioprotective effect.

Other NSAIDs: Phenylbutazone, indomethacin, salicylates (e.g., aspirin), and other NSAIDs (e.g., mefenamic acid, naproxen, diclofenac, ketoprofen), including cyclooxygenase (COX)-2 inhibitors (e.g., celecoxib, etoricoxib), increase the risk of stomach and intestinal bleeding in patients receiving ibuprofen.

Aminoglycosides: NSAIDs, such as ibuprofen, increase aminoglycoside toxicity by decreasing the excretion of aminoglycoside antibiotics (e.g., amikacin, gentamicin, neomycin, tobramycin).

Antacids: The plasma levels of ibuprofen may be increased when taken together with antacids such as magnesium hydroxide.

Antihypertensives and Diuretics: NSAIDS may reduce the effect of these drugs (e.g., captopril, enalapril, losartan, telmisartan); diuretics (e.g., furosemide) may also cause acute reduction in kidney function of NSAIDs

Blood Thinning Medicines (Anticoagulants): When taken with blood thinning (anticoagulant) medicines (e.g., warfarin, dicumarol) or together with thrombolytic agents (e.g., streptokinase), ibuprofen may cause stomach and intestinal bleeding.

Cardiac Glycosides: NSAIDs may worsen heart failure, reduce kidney function and increase blood levels of these medicines (e.g., digoxin)

Cholestyramine: May reduce the absorption of ibuprofen

Ciclosporin and Tacrolimus: Increased risk of kidney damage

Corticosteroids, Selective Serotonin-Reuptake Inhibitors (SSRIs), and Anti-platelet Agents: May increase the risk of stomach bleeding with ibuprofen

Ginkgo biloba: May enhance the risk of bleeding when given with ibuprofen

Lithium and Methotrexate: Ibuprofen increases the amount of lithium and methotrexate in the blood, thus increasing the risk of toxicity

Medicines Affecting Liver Enzymes: Medicines which hinder the enzymes responsible for the metabolism of ibuprofen may alter its safety and efficacy

Medicines that Lower Blood Sugar (for Diabetes): Ibuprofen may increase plasma levels of medicines used to treat diabetes (sulfonylureas such as gliclazide, glipizide, glimepiride) and insulin by inhibiting their metabolism.

Probenecid: May reduce the metabolism and excretion of ibuprofen, thus increasing the risk of ibuprofen toxicity.

Quinolone Antibiotics: A possible increased risk of convulsions may occur with ibuprofen

Zidovudine: An increased risk of blood problems such as bleeding into a joint (hemarthrosis) and bruising (hematoma) may result when given with ibuprofen

Tell your doctor if you are taking other medicines, including vitamins, supplements, and herbal medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, take the next dose as soon as you remember if still needed for pain and/or fever or inflammation. If it is almost time to take the next dose, wait until then to take your medicine and skip your missed dose.

Do not double the dose and do not exceed the maximum dose in 24 hours.

HOW SHOULD YOU KEEP THIS MEDICINE?

Keep the product out of sight and reach of children.
Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

The most frequently reported symptoms of ibuprofen overdose include abdominal pain, nausea, vomiting, fatigue (lethargy), and drowsiness. Other symptoms include headache, ringing in the ears (tinnitus), central nervous system depression, convulsions, low blood pressure, and irregular heartbeat. Excessive acidity of the blood (metabolic acidosis), coma, acute kidney failure, too much potassium in the blood (hyperkalemia), absence of spontaneous breathing (apnea), respiratory depression, and respiratory failure may rarely occur.

WHAT TO DO WHEN YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE?

If more than the recommended dosage has been given, consult a doctor or contact a Poison Control Center right away.

CARE THAT SHOULD BE TAKEN WHEN USING THIS MEDICINE

- Ibuprofen may make you feel dizzy or drowsy. If it affects you in this way, do not drive, operate machinery or do anything that requires you to be alert.
- **Allergy Alert:** Ibuprofen may cause a severe allergic reaction which may include:
  - Hives (elevated, whitish or reddish patches on the skin with severe itching or pricking sensations);
  - Shock (anaphylactic), a hypersensitivity reaction resulting to generalized skin lesions and itchiness, followed by vascular collapse and often accompanied by life-threatening respiratory distress
  - Facial swelling
  - Skin reddening
  - Asthma (wheezing)
  - Skin rash or skin blisters
- **Stomach Bleeding Warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:
  - Have had stomach ulcers or bleeding problems
  - Take a blood thinning (anticoagulant) or steroid medicine
  - Take other medicines containing prescription or nonprescription NSAIDs (aspirin, ibuprofen or others)
  - Take more or for a longer time than directed
- The risk of heart attack or stroke may increase if you use more than or longer than directed.
- Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Ask a doctor before use if you or the child is:
- Having problems or serious side effects from taking pain relievers or fever reducers
- Taking aspirin or other NSAIDs
- Taking other medicines
- Under a doctor's care for any serious condition

Ask a doctor before use if:
- Stomach bleeding warning applies to you or the child
- You or the child has heart problems, previous stroke or might be at risk of these conditions (e.g., high blood pressure, high cholesterol, diabetes, or if you are a smoker)
- You or the child has a history of stomach problems, such as heartburn, Crohn's disease (inflammation of the digestive system) or ulcerative colitis (ulcers in the lining of the rectum and colon)
- You or the child has blood clotting disorder (e.g., hemophilia)
- You or the child has liver or kidney problems
- You or the child has asthma
- You or the child is taking a diuretic
- You or the child has a connective tissue disease (autoimmune diseases affecting connective tissue)
- You are 12 to 18 years old, as there is a risk of renal impairment, especially if you have not been drinking fluids or has lost fluids due to continuous vomiting or diarrhea

Stop use and ask a doctor if:
- You or the child experiences any of the following signs of stomach bleeding:
  - Feel faint
  - Vomit blood or dark particles that look like coffee grounds
  - Have bloody or black stools
  - Have stomach pain that does not get better
- An allergic reaction occurs
- New symptoms occur
- Symptoms do not get better
- Redness or swelling is present in the painful area
- The child does not get any relief within 24 hours of treatment
- Pain gets worse or lasts more than 10 days in adults or 3 days in children

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph **AND** Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Dolan® FP 40 mg/mL Suspension (Oral Drops) (DR-XY45937)
- in HDPE bottle of 15mL
Dolan® FP 100 mg/5mL Suspension (DR-XY23908)
- in HDPE bottle of 60mL
Dolan® FP Forte 200 mg/5mL Suspension (DR-XY30816)
- in HDPE bottle of 60mL

DATE OF FIRST AUTHORIZATION (DR-XY45937): June 2017
DATE OF FIRST AUTHORIZATION (DR-XY23908): December 2010
DATE OF FIRST AUTHORIZATION (DR-XY30816): December 2010

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