Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed without a physician's prescription

Panadol™, film coated tablets, 500 mg

Each film coated tablet contains: paracetamol 500 mg

List of the additional ingredients detailed in section 6.

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the pharmacist.

The medicine is not recommended for children under the age of 6 years, except on medical advice.

1. What is the medicine intended for?

Panadol tablets are used for lowering fever and pain relief.

For treatment of headaches, musculoskeletal disorders, menstrual pain and toothache.

Therapeutic group

analgesic and antipyretic

2. Before using the medicine

Do not use the medicine:

- **if you have ever had an allergic reaction** to paracetamol or to any of the additional ingredients (listed in Section 6).
- if you are **taking other medicines containing paracetamol.**
- if you are **under 6 years** unless your physician tells you to.

Special warnings regarding the use of the medicine

Before the treatment with Panadol, tell the physician:

- if you have **severe liver** or **kidney disease,** including **alcoholic liver disease.**

Paracetamol may cause liver damage when:

- given at a dose higher than recommended or for a prolonged period.
- drinking alcoholic beverages during treatment.
- taking other medicines which affect liver function.

Don't take other medicines for lowering fever and pain relief or cold medicines without consulting a physician or pharmacist for prevention of paracetamol overdose or toxicity.

Avoid taking a high dose (within the recommended range) of this medicine when fasting.

If you are taking other medicines

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. Especially if you are taking:

- anticoagulants especially warfarin
- medicines with stimulate production of liver enzymes (e.g. barbiturates)
- antiepileptics - phenytoin, carbamazepine
- nonsteroidal anti-inflamatory drugs
- metoclopramide or domperidone (for the treatment of nausea, vomiting and other digestive problems)
- chloramphenicol or rifampicin (antibiotics)
- probenecid (for the treatment of gout)
- cholestyramine (to reduce excessive blood fats).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding consult with a physician before commencing treatment with this medicine.

3. How should you use the medicine?

You should check with the physician or the pharmacist if you are unsure.

The usual dosage is:

Adults, elderly, and children aged 12 years and over:

1-2 tablets every 4-6 hours as needed.

Be sure to keep intervals of at least 4 hours between doses.

Do not take more than 8 tablets in 24 hours.

Children aged 6-12 years:

1/2-1 tablet every 4-6 hours as needed.

Be sure to keep intervals of at least 4 hours between doses.

Do not give more than 4 tablets in 24 hours.

Not recommended for children under 6 years except on medical advice.

- **Do not take for more than three days without consulting your physician.**
- **Do not take more than the recommended dose.**
- **If symptoms persist consult your physician.**
- **Prolonged use except under medical supervision may be harmful.**

If you take too many tablets

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you. Even if you feel well, immediate treatment is essential, **due to the risk of developing severe liver damage.** Side effects can include nausea and vomiting, diarrhea, loss of appetite, abdominal pain, swelling, excessive sweating, pain or sensitivity in the upper abdomen and they may not reflect the severity of liver damage.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. Side effects

As with any medicine, use of Panadol may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

Stop taking this medicine and tell your physician immediately if:

- you experience allergic reactions such as skin rash or itching, sometimes with breathing or swallowing problems or swelling of the lips, tongue, throat or face.
- you experience a severe skin rash or peeling of the skin which may be accompanied by mouth ulcers.
- you may have previously experienced breathing problems with aspirin or non-steroidal anti-inflammatories, and experience a similar reaction to this product.
- you experience unexplained bruising or bleeding or developing inflammations more easily.

These reactions are rare.

If a side effect has appeared, if any of the side effects get worse or when you suffer from a side effect that has not been mentioned in the leaflet, you should consult the physician.

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.

Do not store above 25°C.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

6. Additional information

- In addition to the active ingredient the medicine also contains:
  pregelatinised starch, maize starch, talc, stearic acid, povidone, potassium sorbate, hypromellose and triacetin.
- What does the medicine look like and what is the content of the package -
  Panadol tablets are white, film-coated tablets with flat edges with a triangular logo embossed on one side and a break line on the other side.

Panadol tablets are produced in packs of 8, 10, 12, or 20 tablets.

Not all pack sizes may be marketed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline Dungarvan Ltd., Dungarvan, Ireland.
- This leaflet was checked and approved by the Ministry of Health in: June 2015
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