Package Leaflet: Information for the User

Read all of this leaflet carefully before you start

Always take this medicine exactly as described in

this leaflet or as your doctor or pharmacist has told

Keep this leaflet. You may need to read it again.

If you get any side effects, talk to your doctor or

You must talk to a doctor if you do not feel better

WHAT IS IN THIS LEAFLET

1. What Paracetamol Tablets is and what it

2. What you need to know before you take

Contents of the pack and further information

. WHAT PARACETAMOL TABLETS IS AND WHAT IT IS USED FOR

belongs to a group of medicines called Analgesics

the treatment of mild to moderate pain including

symptomatic relief of sprain, strain and rheumatic

They also reduce temperature and used for the

if you are allergic to paracetamol or any of the

If you are taking any other medicines that contain

symptomatic relief of feverishness, feverish colds

headache, migraine, neuralgia (severe pain in

nerves), toothache, period pains and the

3. How to take Paracetamol Tablets

5. How to store Paracetamol Tablets

Each Tablet contains 500 mg of the active

Paracetamol Tablets are used for

Do not take Paracetamol Tablets:

other ingredients (listed in Section 6).

ingredient Paracetamol. Paracetamol tablets

pharmacist. This includes any possible side

effects not listed in this leaflet. See section 4.

taking this medicine because it contains

Ask your pharmacist if you need more

important information for you.

information or advice.

is used for

and Antipyretics.

and influenza.

Paracetamol Tablets

4. Possible side effects

or you feel worse after 3 days.

Paracetamol 500mg Tablets (FPL) (POM)

XXX

if you have severe kidney or liver problems including non-cirrhotic alcoholic liver disease if you have non-serious arthritis and need to take painkillers everyday

Take special care before taking Paracetamol

Other medicines and Paracetamol Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines obtained without a

- Chloramphenicol (an antibiotic): paracetamol may increase the levels of chloramphenicol in the blood
- Anticoagulant to thin your blood such e.g. warfarin
- Medicines to control nausea and vomiting e.g. Metoclopramide or domperidone Medicines to control high lipid levels

e.g. Colestyramine

# Taking Paracetamol Tablets with alcohol

You should not drink alcohol whilst taking Paracetamol Tablets. Taking alcohol with paracetamol can increase your chances of getting

# Pregnancy and breast-feeding:

If necessary, Paracetamol 500 mg Tablets can be used during pregnancy. You should use the lowest possible dose that reduces your pain and/or your fever and use it for the shortest time possible. Contact your doctor if the pain and/or fever are not reduced or if you need to take the medicine more

Tell your doctor if you are pregnant or planning to become pregnant, or are breast-feeding. Ask your doctor or pharmacist for advice before taking any other medicine.

#### Paracetamol Tablets contains Sodium Metabisulphite.

Paracetamol Tablets contain sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm (breathing difficulties).

# 3. HOW TO TAKE PARACETAMOL

Always take Paracetamol tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For oral administration and short term use only. Swallow the tablets with water.

### Adults, the elderly and children 16 years or older

# 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACETAMOL TABLETS E00mm m 4mh lm4 Haw Offen

Age	Souring tablet	How Oilen
16 years and over	One -Two	Do not take more than 8 tablets per day (24 hours).

# Children:

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Age	500mg tablet dose	How Often				
6-8 years	Half	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours				
8-10 years	Half	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours				
10-12 years	One	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours				
12 <b>-</b> 15 years	One-One & half	Every 4-6 hours when necessary to a maximum of 4 doses in 24 hours				

#### Paracetamol Tablets should not be given to children under 6 years of age.

#### If you take more Paracetamol than you should Talk to your doctor even if you feel well because

of the risk of delayed, serious liver damage Always take any tablets left over with you, also the box and leaflet as this will allow easier

#### If you forget to take Paracetamol Tablets:

If you forget to take a dose, take it as soon as you remember. However, do not take a double dose to make up for a forgotten dose.

Remember to leave at least 4 hours between

# 4. POSSIBLE SIDE EFFECTS

identification of the tablets

Like all medicines, Paracetamol can cause side effects, although not everybody gets them,

If you experience any of the following serious effects STOP taking this medicine immediately and contact your doctor or pharmacist:

# Severe allergic reactions include:

- difficulty in breathing
- skin rash and itching
- swelling of the face and throat
- runny nose

Rare cases of serious skin reactions have been reported with symptoms like skin reddening, blisters or rash.

# Other possible side effects

If any of the following side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist:

- Occasionally the blood does not clot well, which may result in easy bruising or bleeding.
- Rarely, a severe reduction in the number of white blood cells, which makes infections more likely.
- Nausea, sudden weight loss, loss of appetite, abdominal pain and swelling, dark colored urine or stools and vellowing of skin and eyes

#### Reporting of side effects

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If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA yellow card in Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE PARACETAMOL TABLETS

- This medicinal product does not require any special storage conditions.
- Do not use your tablets after the expiry date stated on the label or carton.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment
- Keep this medicine out of the sight and reach of

# 6. CONTENTS OF THE PACK AND FURTHER INFORMATION

#### What Paracetamol Tablets contains

These tablets contain 500 mg of Paracetamol as the active ingredient.

They also contain pregelatinised starch, magnesium stearate (E572), stearic acid (E570) and sodium metabisulphite (E223).

## What Paracetamol Tablets look like and contents of the pack.

Paracetamol Tablets are white to off white, circular flat bevelled edge tablet with a breakline on one side and plain on the other.

The tablet can be divided into equal doses. Paracetamol Tablets are available in blister packs of 100 tablets.

#### Marketing Authorisation Holder Flamingo Pharma (UK) Ltd.

1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, UK.

# Manufacturer:

Flamingo Pharma (UK) Limited, The Bloc,

38 Springfield Way, Anlaby, Hull, HU10 6RJ, United Kingdom

If you would like this leaflet in different format information or want to report any side effects please contact marketing authorisation holder listed above.

This leaflet was last revised in September 2020.

# POM

MPLLPAR0500TBCOM PL 43461/0003

Code: MPLLPAR0500TBCOMFPLXXX024V03

Colour Scheme: Black

Ref. Artwork: MDLI DADOGOOTDCOMEDI VVVO24V02

Customer / Livery: FPL UK

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