

**PARACETAMOL 500MG SOLUBLE TABLETS
PL 30464/0006**

UKPAR

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PARACETAMOL 500MG SOLUBLE TABLETS
PL 30464/0006

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency granted Athlone Pharmaceuticals Limited a Marketing Authorisation (licence) for the medicinal product Paracetamol 500mg Soluble Tablets (PL 30464/0006) on 3rd August 2010. This is a prescription-only medicine (POM).

Paracetamol is an analgesic (relieves pain) and antipyretic (lowers your temperature when you have a fever). Paracetamol 500mg Soluble Tablets are used to relieve headache, migraine, rheumatic or muscular pain, neuralgia, toothache, period pain and symptoms of colds and flu.

This application is identical of a previously granted application for Paracetamol 500mg Soluble Tablets (PL 15582/0005), authorised to Zanza Healthcare on 26th February 2002. The test and reference products are identical and can be used interchangeably.

No new or unexpected safety concerns arose from this simple application and it was, therefore, judged that the benefits of taking Paracetamol 500mg Soluble Tablets outweigh the risks; hence a Marketing Authorisation has been granted.

**PARACETAMOL 500MG SOLUBLE TABLETS
PL 30464/0006**

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Athlone Pharmaceuticals Ltd a Marketing Authorisation (licence) for the medicinal product Paracetamol 500mg Soluble Tablets (PL 30464/0006) on 3rd August 2010. This product is indicated for the relief of head aches, migraine, rheumatic and muscular pain, neuralgia, toothache and period pain, and to relieve the symptoms of colds and flu.

The application was submitted as a simple abridged “informed consent” application according to Article 10c of Directive 2001/83/EC (as amended), cross-referring to Paracetamol 500mg Soluble Tablets (PL 15582/0005), authorised to Zanza Healthcare on 26th February 2002 and which was subsequently cancelled on 20th July 2007. This is still considered a valid reference product as submission of the abridged application was made before the cancellation took place.

The product is available in pack sizes of 60 and 100 tablets. Pack sizes of products containing paracetamol of greater than 32 tablets are classified as prescription-only (POM).

Paracetamol is a peripherally acting analgesic with antipyretic activity. Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1-4 hours. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose-dependant.

No new data were submitted nor were they necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) has been generated for it.

The pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

The marketing authorisation holder has provided adequate justification for not submitting a Risk Management Plan (RMP) and Environmental Risk Assessment (ERA).

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 30464/0006

PROPRIETARY NAME: Paracetamol 500mg Soluble Tablets

ACTIVE: Paracetamol

COMPANY NAME: Athlone Pharmaceuticals Ltd.

E.C. ARTICLE: Article 10c of Directive 2001/83/EC

LEGAL STATUS: POM

1. INTRODUCTION

This is a simple, informed consent application for Paracetamol 500mg Soluble Tablets submitted under Article 10c of Directive 2001/83/EC. The proposed Marketing Authorisation Holder is Athlone Pharmaceuticals Ltd., Ballymurray, County Roscommon, Ireland.

The application cross-refers to Paracetamol 500mg Soluble Tablets (PL 15582/0005), authorised to Zanza Healthcare on 26th February 2002 and cancelled on 20th July 2007. However this is still considered a valid reference product as submission of the abridged application was made before the cancellation took place. The current application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Paracetamol 500mg Soluble Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The medicinal product is presented as a round, biplane, white or off-white tablet with facets on both sides. The tablets are marketed in a polypropylene tube with polyethylene stopper containing silica gel as desiccant. The tubes are packaged with the Patient Information Leaflet (PIL) into an outer carton in pack sizes of 60 and 100 tablets.

All primary product packaging complies with EU legislation regarding contact with food. The proposed shelf-life is 3years. Storage conditions for the product are “Do not store above 25°C” and “Keep the container tightly closed”. The shelf-life and storage conditions are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, this product will be available as a prescription-only medicine (POM). Pack sizes of more than 32 capsules are POM.

2.4 Marketing authorisation holder/Contact Persons/Company

Athlone Pharmaceuticals Ltd., Ballymurray, County Roscommon, Ireland.

The QP responsible for pharmacovigilance is stated and his CV has been provided.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specification

The proposed finished product specification is in-line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

With the exception of lactose monohydrate, none of the excipients contain materials of animal or human origin. The supplier of lactose monohydrate has provided a declaration that milk used in the production of lactose monohydrate is sourced from healthy animals under the same conditions as those intended for human consumption. No genetically modified organisms (GMO) have been used in the preparation of this product. This is consistent with the cross-reference product.

3. EXPERT REPORTS

A satisfactory expert report and curriculum vitae of the expert are provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is consistent with that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/CARTON

PIL

The PIL has been prepared in the user tested format and in-line with the details registered for the cross-reference product. The approved PIL is satisfactory.

Carton and label

Colour mock-ups of the labelling have been provided and are satisfactory. The approved artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. The applicant has included the name of the product in Braille on the outer packaging and the carton includes sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with this application is acceptable. A Marketing Authorisation was, therefore, granted.

PRECLINICAL ASSESSMENT

As this application is identical to the reference product Paracetamol 500mg Soluble Tablets (PL 15582/0005), no new preclinical data have been supplied with this application and none are required. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

The marketing authorisation holder has provided adequate justification for not submitting an Environment Risk Assessment (ERA). As these applications are identical to an already authorised reference product, it is not expected that the environmental exposure to paracetamol will increase following the marketing approval of the proposed product.

CLINICAL ASSESSMENT

As this application is identical to the reference product Paracetamol 500mg Soluble Tablets (PL 15582/0005), no new clinical data has been supplied with this application and none are required. A clinical expert report has been written by a suitably qualified person and is satisfactory.

The marketing authorisation holder (MAH) has provided adequate justification for not submitting a Risk Management Plan (RMP). As this application is identical to an already authorised reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active is well-established.

The MAH has provided a suitable pharmacovigilance system that fulfils the requirements and provides adequate evidence that the MAH has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with those previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to the previously granted application for Paracetamol 500mg Soluble Tablets (PL 15582/0005) licensed to Zanza Healthcare.

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SmPC, PIL and labelling are satisfactory, and consistent with those for the cross-reference product.

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to two parent PILs; Paldesic 120mg/5ml Oral Suspension authorised to Rosemont Pharmaceuticals Ltd and Quinine Sulphate Tablets BP 300mg (for in-house style and formatting) and to a brand PIL referring Paracetamol 500mg Soluble Tablets authorised to Wintrop Pharmaceuticals (PL 17780/0162). The bridging report submitted by the applicant has been found acceptable.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. The name of the product in Braille appears on the outer packaging.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-reference product. Extensive clinical experience with paracetamol is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

**PARACETAMOL 500MG SOLUBLE TABLETS
PL 30464/0006**

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on 18 th May 2007.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 6 th May 2009.
3	Following assessment of the application the MHRA requested further information relating to the quality dossier on 14 th October 2009, 11 th March 2010, 25 th March 2010 and 10 th May 2010.
4	The applicant responded to the MHRA's requests, providing further information on 14 th December 2009, 22 nd March 2009, 12 th April 2010 and 17 th June 2010.
5	The application was determined on 3 rd August 2010.

**PARACETAMOL 500MG SOLUBLE TABLETS
PL 30464/0006**

STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

PARACETAMOL 500MG SOLUBLE TABLETS

PL 30464/0006

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Paracetamol 500mg Soluble Tablets (PL 30646/0006) is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 500mg Soluble Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains:

Paracetamol 500mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablets

Round, biplane, white or off- white tablets with facets on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of mild to moderate pain including headache, migraine, neuralgia, toothache, period pain and pain caused by rheumatism.

It is also used to relieve the symptoms of colds, flu and sore throats.

4.2 Posology and method of administration

Adults and children over 12 years:

One or two tablets to be taken every four to six hours if necessary. Do not exceed 8 tablets in 24 hours.

Not to be given to children under 12 years.

Elderly patients:

Normal adult dose unless there is impaired kidney or liver function.

Directions:

The tablets must be dissolved in a glass of water. The tablets dissolve more quickly in warm water if stirred.

4.3 Contraindications

Caution should be taken in patients with impaired kidney or liver function, or previous hypersensitivity to paracetamol or other ingredients.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special warnings and precautions for use

Should be taken with caution in patients with impaired liver and kidney function.

The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Do not exceed the stated dose.

Not to be given to children under 6 years, without medical advise. Dosage should not be continued for more than three days without consulting your doctor.

If symptoms persist, consult your doctor.

Do not take with any other paracetamol-containing products.

Keep all medicines out of the reach of children.

Label:

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Leaflet or combined Label/Leaflet:

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

4.6 Pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of the doctor regarding its use.

4.7 Effects on ability to drive and use machines

No special comment-unlikely to produce an effect.

4.8 Undesirable effects

Side-effects are usually mild and may include skin rashes and other allergic reactions occasionally. Very rarely there have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily related to paracetamol.

4.9 Overdose

Symptoms of overdosage: Pallor, anorexia, nausea, vomiting and abdominal pain are frequent early symptoms of paracetamol overdosage.

Hepatic necrosis is a dose-related complication of paracetamol overdose. Hepatic enzymes may become elevated and prothrombin time prolonged within 12 to 48 hours but clinical symptoms may not be apparent for 1 to 6 days after ingestion. Toxicity is likely in subjects who have taken single doses of 10 g (150mg/kg) or more. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue.

Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

In paracetamol overdosage with liver cell damage, paracetamol half-life is often prolonged from around 2 hours in normal adults to 4 hours or longer. However, liver cell damage has been found in patients with a paracetamol half-life less than 4 hours. Diminution of ¹⁴C₀₂ excretion after ¹⁴C-aminopyrine has been reported to correlate better with liver cell damage in paracetamol overdosage than do either plasma paracetamol concentration or half-life, or conventional liver function test measurements. Renal failure due to acute tubular necrosis may follow paracetamol-induced fulminant hepatic failure. The incidence of this is, however, no more frequent in these patients than in others with fulminant hepatic failure from other causes.

Therapeutic measures in overdosage:

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of

significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who had ingested around 7.5 g or more of paracetamol in the preceding 4 hours should undergo gastric lavage.

Administration of oral methionine or intravenous N-acetylcysteine which may have beneficial effect up to at least 48 hours after overdose, may be required. General supportive measures must be available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: N02B E01

Paracetamol has analgesic and antipyric effects similar to those of aspirin and is useful in the treatment of mild to moderate pain. It has weak anti-inflammatory effects.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations are reached 30-90 minutes post dose and the plasma half-life is in the range of 1 to 3 hours after therapeutic doses. Drug is widely distributed throughout most body fluids. Following therapeutic doses 90-100% of the drug is recovered in the urine within 24 hours almost entirely following hepatic conjugation with glucuronic acid (about 60%), sulphuric acid (about 35%) or cysteine (about 3%). Small amounts of hydroxylated and deacetylated metabolites have been detected. Children have less capacity for glucuronidation of the drug than do adults. In overdosage there is increased N- hydroxylation followed by glutathione conjugation. When the latter is exhausted, reaction with hepatic proteins is increased leading to necrosis.

5.3 Preclinical safety data

Acute Toxicity Paracetamol hepatotoxicity is directly dependent on the plasma concentration related to time. Plasma concentrations above 1.2 mmol/l at 4 hours, 0.6 mmol/l at 8 hours and 0.3 mmol/l at 12 hours are criteria for treatment with acetylcysteine to prevent irreversible liver damage.

Chronic toxicity In animal experiments the subchronic and chronic toxicity of paracetamol occurred in rats and mice as lesions in the gastro-intestinal tract, blood-count changes, degeneration and even necrosis of the hepatic and renal parenchyma. The metabolites that are assumed to have the toxic effects and the organic changes associated with them have been proven in humans as well.

Therefore, paracetamol should not be taken for a long period of time and in excessive doses. Oral daily doses with clearly hepatotoxic effects are around 5.8 g for non-alcoholics, symptoms of intoxication can occur as soon as 3 weeks after administration.

Mutagenic and tumorigenic potential in mammalian cell cultures paracetamol induces chromosome mutations depending on its concentration. In-vivo tests show negative as well as slightly positive results. Due to the insufficient relevance of the most part of the in-vivo tests no final evaluation is possible at this time.

Long-term studies in rats and mice have yielded no indications of a carcinogenic effect.

Reproductive toxicology Paracetamol passes the placental barrier. Animal studies and experience to date in humans reveal no evidence of embryotoxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid
Sodium sulphate
Lactose monohydrate
Sodium hydrogen carbonate
Povidone
Simethicone emulsion
Saccharin sodium
Lemon flavour
Macrogo16000
Water
Isopropanol

Sodium content approximately 392 mg per tablet.

- 6.2 Incompatibilities**
Not applicable
- 6.3 Shelf life**
3 years
- 6.4 Special precautions for storage**
Do not store above 25°C. Keep the container tightly closed.
- 6.5 Nature and contents of container**
Polypropylene tube with polyethylene stopper containing silica gel as desiccant. The tubes are packed into an outer carton.
- Pack sizes: 60 and 100.
- 6.6 Special precautions for disposal**
None.
- 7 MARKETING AUTHORISATION HOLDER**
Athlone Pharmaceuticals Ltd.
Ballymurray
Co. Roscommon
Ireland
- 8 MARKETING AUTHORISATION NUMBER(S)**
PL 30464/0006
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
03/08/2010
- 10 DATE OF REVISION OF THE TEXT**
03/08/2010

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

PARACETAMOL 500mg SOLUBLE TABLETS



Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IN THIS LEAFLET

1. What your medicine is and what it is used for
2. Before you take your medicine
3. How to take your medicine
4. Possible side effects
5. How to store your medicine
6. Further information

1. WHAT YOUR MEDICINE IS AND WHAT IT IS USED FOR

The name of your medicine is Paracetamol 500mg Soluble Tablets. The active ingredient in your medicine is paracetamol.

Paracetamol is an analgesic, which means it acts as a painkiller. It is used to treat:

- nerve pain (neuralgia)
- toothache
- period pain
- headaches, including migraine
- relieving the fever, aches and pains of colds and flu
- rheumatic pain and muscle pain

2. BEFORE YOU TAKE YOUR MEDICINE

DO NOT TAKE Paracetamol 500mg Soluble Tablets if you:

- are allergic (hypersensitive) to paracetamol or any of the other ingredients in this medicine. Signs of an allergic reaction include a rash, itching, breathing or swelling of the legs, arms, face, throat or tongue
- are under 12 years of age. Paracetamol 500mg Soluble Tablets must not be given to children under 12 years of age.

Do not take Paracetamol 500mg Soluble Tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking paracetamol.

Take special care with this medicine if you:

- are taking other medicines containing paracetamol
- have severe kidney or liver problems
- have a liver problem caused by alcohol

Speak to your doctor or pharmacist if any of the above apply to you as you may be more at risk of the side effects of Paracetamol.

Important information about some of the ingredients in your medicine

Your medicine contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicinal product contains approximately 392mg of sodium per tablet. To be taken into consideration by patients on a controlled sodium diet.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you have bought without a prescription, including herbal medicines.

You must not take any other medicines that contain paracetamol while you are taking this medicine.

Please check with your doctor or pharmacist if you are taking any of the following:

- metoclopramide or domperidone (used to treat nausea and vomiting)
- colestyramine (used to treat high cholesterol)
- anti-coagulants (used to thin the blood e.g. warfarin)

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant, or are breast-feeding talk to your doctor or pharmacist before taking this medicine.

Driving and using machines

This medicine should not affect your ability to drive or use machines.

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3. HOW TO TAKE YOUR MEDICINE

Always take Paracetamol exactly as it says in this leaflet. You should check with your doctor or pharmacist if you are not sure.

- Do not take more than the recommended dose.
- If you need to use this medicine for more than three days at a time, see your doctor.

Taking this medicine

- Dissolve the tablets in a glass of water before taking.

Adults and children over 12 years

The usual dose of paracetamol is 1 or 2 tablets up to four times a day as required.

- Wait at least 4 to 6 hours before taking another dose
- Do not take more than four doses in any 24 hour period
- If symptoms persist for more than 3 days or get worse contact your doctor

Children under 12 years of age

These tablets are not recommended for children under 12 years of age.

If you take more paracetamol than you should

Tell your doctor or go to your nearest hospital casualty department straight away- even if you feel well. This is because of the risk of delayed serious liver damage. Remember to take any remaining tablets and the pack with you. This is so the doctor knows what you have taken.

If you have forgotten to take Paracetamol

If you forget to take a dose at the right time, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take two doses at or near the same time. Remember to leave at least 4 hours between doses.

4. POSSIBLE SIDE EFFECTS

As with all medicines, paracetamol can cause side effects, although not everybody gets them.

Stop taking paracetamol and see a doctor or go to a hospital as soon as possible if you notice any of the following:

- swelling of the hands, feet, ankles, face, lips or throat, which may cause difficulty in swallowing or breathing. You could notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to paracetamol.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days:

- you get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia). These are very rare side effects in people taking paracetamol.

If any of the side effects gets serious, lasts longer than a few days or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE YOUR MEDICINE

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Do not use after the expiry date stated on the label.

Do not store above 25°C. Keep the container tightly closed.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What your medicine contains

Each tablet contains 500mg of the active ingredient paracetamol.

The other ingredients are citric acid, sodium sulphate, lactose monohydrate, sodium hydrogen carbonate, povidone, simethicone emulsion, saccharin sodium, lemon flavour, macrogol, water and isopropanol.

What your medicine looks like and the contents of the pack

Paracetamol 500mg Soluble Tablets are round, biplane, white or off-white tablets with facets on both sides.

The tablets are available in containers of 60 and 100 tablets.

Marketing Authorisation Holder

Athlone Pharmaceuticals Limited, Ballymurray, Co. Roscommon, Ireland.

Distributor

Kent Pharmaceuticals Limited, Wotton Road, Ashford, Kent, TN23 6LL, U.K.

PL 30464/0006

This leaflet was last revised June 2010.

A1645V1P5

LABELLING

BOTTLE LABEL (PL 00156/0320)

