Safeguarding public health

MHRA

Public Assessment Report

Indapamide 2.5mg Tablets

PL 13606/0118

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

UKPAR

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INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Co-Pharma Limited a Marketing Authorisation (licence) for the medicinal product Indapamide 2.5mg Tablets (PL 13606/0118). This is a prescription only medicine [POM] for treating high blood pressure.

Indapamide works by increasing the volume of urine produced by the kidneys, thus helping to remove excess fluids from the body.

This is a simple abridged application that cross-refers to a previously granted licence for Indapamide Tablets 2.5mg (PL 00790/0102).

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Indapamide 2.5mg Tablets outweigh the risks, hence a Marketing Authorisation has been granted.

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Indapamide 2.5mg Tablets (PL 13606/0118) to Co-Pharma Limited on 27 March 2006. The product is a prescription only medicine [POM].

This application was submitted as a simple abridged application according to Article 10.1(a)i of Directive 2001/83/EC, as amended, cross-referring to Indapamide Tablets 2.5mg (PL 00790/0102, approved on 2 November 1993).

The product contains indapamide. Indapamide is an indoline derivative of chlorsulfonamide which shares many chemical, pharmacodynamic and therapeutic similarities with other sulfonamide diuretics. In addition to its diuretic activity indapamide has been shown to decrease vascular smooth muscle reactivity and peripheral resistance in various *in vitro* and *in vivo* models.

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

Indapamide 2.5mg Tablets is used for the treatment of essential hypertension.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: **PL 13606/0118**
PROPRIETARY NAME: **Indapamide 2.5mg Tablets**
ACTIVE(S): **Indapamide**
COMPANY NAME: **CO-PHARMA LIMITED**
E.C. ARTICLE: **2001/83/EC 10.1(a)(i)**
LEGAL STATUS: **POM**

INTRODUCTION

This is a simple, national "piggyback" application which cross-refers to PL 00790/0102, the MA holder of which is Clonmel Healthcare Limited (first granted a licence on 2 November 1993 and renewed on 6 October 2000). The cross-referenced product was subject to an outgoing MR which was concluded on 29 May 1997.

EXPERT REPORTS

The product is identical in composition, method of manufacture and control to the reference product. No issues or alerts were flagged for the reference product. No significant changes have been made to the licensing particulars. The expert reports (quality, preclinical and clinical) confirm that the product is identical to the cross-referenced product. The pharmaceutical, preclinical and clinical experts are named.

MARKETING AUTHORISATION APPLICATION (MAA) FORM

The recommended storage conditions (Do not store above 25°C. Keep the container tightly closed. Store in the original package) are different from the storage conditions of the cross-referenced product (Store below 25 °C in a dry place) but are in line with current guidelines.

A Qualified Person for pharmacovigilance has been named.

A letter stating that the applicant has access to all preclinical and clinical data supporting the application is available. A declaration that the applicant is in possession of the part II documentation, supplied by the cross-referenced product MAH has also been supplied.

Manufacturing process

This is in line with that of the cross-referenced product.

Finished product specification

This is in line with that of the cross-referenced product.

Drug substance specification

This is in line with that of the cross-referenced product.

SUMMARY OF PRODUCT CHARACTERISTICS

Satisfactory.

PATIENT INFORMATION LEAFLET

Satisfactory.

LABELLING AND PACKAGING

Satisfactory.

Labelling includes a warning concerning sugar content in line with current guidelines.

CONCLUSION

A Marketing Authorisation may be granted.

PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the cross-referenced product and as such have 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 a previously granted application for Indapamide Tablets 2.5mg.

No new or unexpected safety concerns arose from this application.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-referenced product.

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-referenced product. Extensive clinical experience with the active ingredient indapamide is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application for Indapamide 2.5mg Tablets on 22 June 2004.
2	Following standard checks the MHRA informed the applicant that its application was considered valid on 13 July 2004.
3	The MHRA's assessment of the submitted data was completed on 24 January 2005.
4	Further information was requested from the company on 1 February 2005.
5	The applicant submitted its response to further information request on 15 September 2005.
6	Additional information was requested from the company on 23 November 2005.
7	The applicant submitted its response to additional information request on 28 November 2005.
8	The applicant's final labelling details were received by the MHRA on 17 March 2006
9	The MHRA completed its assessment of the application on 17 March 2006.
10	The application was determined on 27 March 2006.

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Indapamide 2.5 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Indapamide 2.5 mg

For excipients see 4.4 and 6.1

3. PHARMACEUTICAL FORM

Coated tablet.

White, biconvex, sugar coated tablet printed with the company logo or printed with "I"

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the treatment of essential hypertension

4.2. Posology and method of administration

Oral use

Adults:

The dosage of one tablet, containing 2.5 mg indapamide, to be taken daily in the morning. The action of indapamide is progressive and the reduction in blood pressure may continue and not reach a maximum until several months after the start of therapy. A larger dose than 2.5 mg of indapamide daily is not recommended as there is no appreciable additional anti-hypertensive effect but a diuretic effect may become apparent. If a single daily tablet of indapamide does not achieve a sufficient reduction in blood pressure, another anti-hypertensive agent may be added such as beta-blockers, ACE inhibitors, methyldopa, clonidine and other adrenergic blocking agents.

Children:

There is no experience of the use of this drug in children.

4.3. Contraindications

Severe renal failure
Hepatic encephalopathy or severe impairment of liver function
Hypokalaemia
Hypersensitivity to sulfonamides, indapamide or any other ingredient.

4.4. Special warnings and precautions for use

***Warnings*:**

When liver function is impaired, thiazide-related diuretics may cause hepatic encephalopathy. Administration of the diuretic must be stopped immediately if this occurs or there are signs of increasing renal insufficiency.

A slight weight loss has been reported in some patients taking indapamide.

Precautions

- Water and electrolyte balance:

***Plasma Sodium**:*

This must be measured before starting treatment, then at regular intervals subsequently. Any diuretics treatment may cause hyponatraemia, sometimes with very serious consequences. The fall in plasma sodium may be asymptomatic initially and regular monitoring is therefore essential, and should be even more frequent in the elderly and cirrhotic patients (See Adverse reactions and Overdose sections).

Plasma Potassium:

Potassium depletion with hypokalaemia is the major risk of thiazide and related diuretics. The risk of onset of hypokalaemia (<3.4mmol/l) must be prevented in certain high risk populations, ie the elderly, malnourished and/or poly-medicated, cirrhotic patients with oedema and ascites, coronary artery disease and cardiac failure patients.

In this latter situation, hypokalaemia increases the cardiac toxicity of digitalis preparations and the risks of arrhythmias. Individuals with a long QT interval are also at risk, whether the origin is congenital or iatrogenic. Hypokalaemia, as well as bradycardia, is then a pre-disposing factor to the onset of severe arrhythmias, in particular, potentially fatal torsades de pointes.

More frequent monitoring of plasma potassium is required in all the situations indicated above. The first measurement of plasma potassium should be obtained during the first week following the start of treatment. Detection of hypokalaemia requires its correction.

Plasma Calcium:

Thiazide and related diuretics may decrease urinary calcium excretion and cause a slight and transitory rise in plasma calcium. Hypercalcaemia may be due to previously unrecognised hyperparathyroidism.

Treatment should be withdrawn before the investigation of parathyroid function.

- Blood Glucose:

Monitoring of blood glucose is important in diabetics, in particular in the presence of hypokalaemia.

- Uric Acid:

Tendency to gout attacks may be increased in hyperuricaemic patients.

- Renal function and diuretics:

Thiazide and related diuretics are fully effective only when renal function is normal or only minimally impaired (plasma creatinine below levels of the order of 25 mg/ml, i.e. 220μmol/l in an adult). In the elderly, this plasma creatinine must be adjusted in relation to age, weight and gender. Hypovolaemia, secondary to the loss of water and sodium induced by the diuretic at the start of treatment causes a reduction in glomerular filtration. This may lead to an increase in blood urea and plasma creatinine. This transitory functional renal insufficiency is of no consequence in individuals with normal renal function but may worsen pre-existing renal insufficiency.

- Athletes:

The attention of athletes is drawn to the fact that this drug contains an active ingredient which may give a positive reaction in doping tests.

- There is no evidence of rebound hypertension on withdrawal of indapamide.

- Patients with rare hereditary problems of fructose or galactose intolerance, the LAPP lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5. Interactions with other medicinal products and other forms of interaction

When indapamide is used in conjunction with carbenoxolone or diuretics such as bumetanide, furosemide, piretanide, thiazides and xipamide, hypokalaemia may result. The co-administration of indapamide with diuretics which may cause hypokalaemia is not recommended. At doses higher than recommended, indapamide has a diuretic effect, therefore it is not recommended for prescription with a diuretic agent which may cause hypokalaemia. No interactions have been reported between indapamide and oral hypoglycaemic agents, anti-coagulants and uricosurics.

If hypokalaemia occurs, the action of digoxin can be potentiated.

Inadvisable combinations:

Lithium:
Increased plasma lithium with signs of overdose, as with a salt-free diet (decreased urinary lithium excretion). However, if the use of diuretics is necessary, careful monitoring of plasma lithium and dose adjustment are required.

Long term treatment with this type of diuretic may reduce excretion of lithium.

Non-antiarrhythmic drugs prolonging the QT interval or causing torsade de pointes (astemizole, IV-erythromycin, halofantrine, pentamidine, sultopride, terfenadine, vincamine):
Torsade de pointes (hypokalaemia is a predisposing factor, the same applying to bradycardia and a pre-existing long QT interval).

Use substances which do not have the disadvantage of causing torsade de pointes in the presence of hypokalaemia.

Combinations requiring precautions:

Digitalis preparations:
Hypokalaemia predisposing to the toxic effects of digitalis.
Monitor plasma potassium, ECG and adjust treatment if necessary.

NSAIDs (systemic), high dose salicylates:
Possible decrease in antihypertensive effect of indapamide.
Acute renal failure in dehydrated patients (decreased glomerular filtration).
Hydrate the patient; monitor renal function at the start of treatment.

Other compounds causing hypokalaemia: amphotericin B (IV), gluco- and mineralocorticoids (systemic), tetracosactide, stimulant laxatives:
Increased risk of hypokalaemia (additive effect).
Monitoring of plasma potassium and correction if required. Must be particularly borne in mind in case of concomitant digitalis treatment. Use non-stimulant laxatives.

Baclofen:
Increased antihypertensive effect.
Hydrate the patient; monitor renal function at the start of treatment.

Combinations which must be taken into consideration:

Potassium-sparing diuretics (amiloride, spironolactone, triamterene):
Such rational combinations, useful in certain patients, do not eliminate the possibility of hypokalaemia or, in particular in renal failure and diabetic patients, of hyperkalaemia.
Monitor plasma potassium, ECG if required and adjust treatment if necessary.

Angiotensin converting enzyme (A.C.E.) inhibitors:
Risk of sudden hypotension and/or acute renal failure when treatment with a converting enzyme inhibitor is started in the presence of pre-existing sodium depletion (in particular in individuals with renal artery stenosis).

In hypertension, when prior diuretic treatment may have caused sodium depletion, it is necessary:
- either to stop the diuretic 3 days before starting treatment with the A.C.E. inhibitor, and restart a hypokalaemia diuretic if necessary;

- or give low initial doses of the A.C.E. inhibitor and increase only gradually. In congestive cardiac failure, start with a very low dose of A.C.E. inhibitor, possibly after a reduction in the dose of the combined hypokalaemic diuretic.
In all cases, monitor renal function (plasma creatinine) during the first weeks of treatment with an A.C.E. inhibitor.

Antiarrhythmic agents causing torsade de pointes: Group1a antiarrhythmic drugs (quinidine, hydroquinidine, disopyramide), amiodarone, bretylium, sotalol:
Torsade de pointes (hypokalaemia is a predisposing factor, the same applying to bradycardia and a pre-existing long QT interval).
Prevention of hypokalaemia and, if necessary, correction; monitoring of QT interval.
In cases of torsade de pointes, do not give antiarrhythmic drugs (management by pacemaker).

Metformin:
In the presence of functional renal insufficiency related to diuretics and more particularly to loop diuretics, increased risk of metformin induced lactic acidosis. Do not use metformin when plasma creatinine exceeds 15 mg/litre (135 μmol/litre) in men and 12 mg/litre (110 μmol/litre) in women.

Iodinated contrast media:
In the presence of dehydration caused by diuretics, increased risk of acute renal failure, in particular when large doses of iodinated contrast media are used.
Rehydration before administration of the iodinated compound.

Imipramine-like antidepressants (tricyclics), neuroleptics:
Antihypertensive effect and risk of orthostatic hypotensive increased (additive effect).

Calcium salts:

Risk of hypercalcaemia resulting from decreased urinary calcium elimination.

Ciclosporin:
Risk of increased plasma creatinine without any change in circulation ciclosporin levels, even in the absence of water/sodium depletion.

Corticosteroids, tetracosactide (systemic):
Decreased antihypertensive effect (water/sodium retention due to corticosteroids).

4.6. Pregnancy and lactation

Pregnancy
As a general rule, the administration of diuretics should be avoided in pregnant women and should never be used to treat physiological oedema of pregnancy. Diuretics can cause foetoplacental ischaemia. with a risk of impaired foetal growth.

Breast feeding

Breast feeding is inadvisable, because indapamide is excreted in human milk.

4.7. Effects on ability to drive and use machines

Diuretics may cause dizziness Occurrence of dizziness may interfere with driving.

4.8. Undesirable effects

The majority of adverse effects concerning clinical or laboratory parameters are dose-dependent.
Thiazide-related diuretics, including indapamide, may cause:

Regarding laboratory parameters

- Potassium depletion with hypokalaemia, particularly serious in certain high risk population (see Precautions).

- Hyponatraemia with hypovolaemia responsible for dehydration and orthostatic hypotension. Concomitant loss of chloride ions may lead to secondary compensatory metabolic alkalosis; the incidence and degree of this effect are slight.

- An increase in plasma uric acid and blood glucose during treatment; a slight reduction in glucose tolerance may occur in patients with diabetes mellitus. Appropriateness of these diuretics must be very carefully weighed in patients with gout or diabetes.

- Haematological events, very rare: thrombocytopenia, leucopenia, agranulocytosis, aplastic anaemia, haemolytic anaemia.

- Hypercalcaemia: extremely rare.

Regarding clinical parameters
- In the presence of hepatic insufficiency, possible onset of hepatic encephalopathy (see Contraindications and Warnings).

- Hypersensitivity reactions, essentially dermatological, in individuals predisposed to allergic and asthmatic manifestations.

- Maculopapular rashes, purpura, possible worsening of pre-existing acute disseminated lupus erythematodes, erythema multiforme and epidermal necrolysis.

- Nausea, constipation, dry mouth, dizziness, vertigo, syncope, fatigue, paraesthesia, muscle cramps, headache, occurring rarely and responding in most instances to a dose reduction.

- Very rarely, pancreatitis.

4.9. Overdose

Expected symptoms of overdosage would be electrolyte imbalance, hypotension, gastrointestinal disturbances and muscular weakness. Treatment would be symptomatic, directed at correcting the electrolyte abnormalities and emesis or gastric lavage should be considered.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

C03B A11 – Low-Ceiling Diuretics, Excl. Thiazides, Sulfonamides, Plain

Indapamide is an indoline derivative of chlorsulfonamide which shares many chemical, pharmacodynamic and therapeutic similarities with other sulfonamide diuretics. In addition to its diuretic activity indapamide has been shown to decrease vascular smooth muscle reactivity and peripheral resistance in various in-vitro and in-vivo models.

5.2. Pharmacokinetic properties

Indapamide is rapidly absorbed from the gastrointestinal tract. Elimination is biphasic with a terminal half-life of 14 to 18 hours. It is extensively metabolised. About 60 to 70% of the dose has been reported to be excreted in the urine; only about 5% is excreted unchanged. About 16-23% of administered dose is excreted in the faeces. Indapamide is about 71 to 79% bound to plasma proteins and it is preferentially taken up in the red blood cells.

5.3. Preclinical safety data

Indapamide has been tested negative concerning mutagenic and carcinogenic properties.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose
Maize Starch
Polyvidone
Magnesium Stearate

Seal coat:
Opaseal (Polyvinylacetate Phthalate, Ethyl Acetate and Stearic Acid)
Purified Talc

Subcoat:
Calcium Carbonate
Acacia
Titanium Dioxide (E171)
Purified Talc
Sucrose

Smoothing Syrup:
Sucrose

Colour Coat:
Sucrose
Titanium Dioxide (E171)

Smoothing Syrup:
Sucrose

Polishing Coat:
Opaglos 6000P (Shellac, Carnauba Wax Yellow and Beeswax White)

6.2. Incompatibilities

None stated

6.3. Shelf life

3 years.

6.4. Special precautions for storage

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

Blisters: Do not store above 25ºC. Store in the original package.

6.5. Nature and contents of container

1. Polypropylene tablet containers with low density polyethylene caps. High density polyethylene film may be used as packing material.

   Pack sizes: 28, 30, 50, 56, 60, 100, 120 and 250 tablets

2. Blister packs consisting of clear PVC and hard temper aluminium foil contained in a carton.

   Pack sizes 28, 30, 50, 56, 60, 100 and 120 tablets

Not all pack sizes may be marketed.

6.6. Instruction for use and handling

None stated.

7. MARKETING AUTHORISATION HOLDER

Co-pharma Limited
Unit 4, Metro Centre
Tolpits Lane
Watford
Herttordshire
WDI 8SS

8. MARKETING AUTHORISATION NUMBER

PL 13606/0118

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/03/2006

10 DATE OF REVISION OF THE TEXT

27/03/2006

Patient Information Leaflet

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

Please read all of this leaflet carefully before you start taking this medicine.
Keep the leaflet, you may need to read it again.
This medicine has been prescribed for you personally, do not pass it on to others. It may harm others even if their symptoms are the same as yours.
If you have any further questions, please ask your doctor or pharmacist.

The name of this medicine is
INDAPAMIDE 2.5 MG TABLETS

The tablets contain 2.5mg of the active substance Indapamide. Other ingredients are lactose, maize starch, polyvidone, magnesium stearate and tablet coating (containing polyvinylacetate phthalate, ethyl acetate, stearic acid, purified talc, calcium carbonate, acacia, titanium dioxide (E171), sucrose, shellac, carnauba wax and beeswax).

Product Licence holder is Co-pharma Ltd., Unit 4, Metro Centre, Tolpits Lane, Watford, Herts, WD1 8SS.
The tablets are manufactured by Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co.Tipperary, Ireland.

What the tablets are and what they are used for
The tablets are white circular sugar coated tablets printed either with the company logo or the letter "I".

Indapamide belongs to a group of drugs called diuretics (also called water tablets). It works by increasing the volume of urine produced by the kidneys, helping to remove excess fluids from the body.

The tablets are supplied to your pharmacist in packs containing 28, 30, 50, 56, 60, 100, 120 and 250 tablets who will then provide you with the required number of tablets as prescribed by your doctor (not all pack sizes may be marketed).

Indapamide is used to treat high blood pressure.

Before you take Indapamide Tablets
Do not take if:
- You are allergic to indapamide, any of the other ingredients or sulfonamides (e.g. trimethoprim).
- You have severe kidney failure.
- You have severe impaired liver function or liver disease.
- You have an abnormally low level of potassium in the blood.

Take special care and check with your doctor before taking if:
- You have liver or kidney impairment.
- You suffer from gout.
- You are pregnant or breast feeding.

This medicine may lower potassium and sodium levels. Your doctor may monitor this by means of blood tests. This may happen in patients receiving multiple treatments, malnourished patients, in the elderly or in those suffering from liver disease, fluid retention, coronary artery disease or heart failure.

Your doctor may monitor blood glucose levels if you are diabetic particularly if you have low potassium levels.

Blood calcium levels may need to be monitored in those patients suffering from overactivity of the parathyroid gland.

Athletes should be aware that this medicine may give a positive reaction in doping tests.

In dehydrated patients this medicine may increase the risk of acute kidney failure if large doses of iodine are used for taking x ray pictures.

This medicine may cause dizziness. If affected do not drive or operate machinery.

Check with your doctor before taking if you are taking any other medicines, including any not prescribed by your doctor, particularly any of the following:
- Any other diuretic medicine (water tablets) used to increase urine output.
- Carbenoxolone.
- Lithium.
- Any of the following drugs which can affect the heart:-
  - Astemizole, terfenadine, erythromycin, halofantrine, pentamidine, sultopride, vincamine.
- Baclofen.
- Metformin.
- Ciclosporin.
- Calcium salts.
- Amphotericin.
- Non-steroidal anti-inflammatory drugs (e.g. ibuprofen) or high doses of salicylates e.g. aspirin.
- Corticosteroids (e.g. hydrocortisone or prednisolone).
- Medicines for heart problems such as digoxin and those used for high blood pressure or for irregular heart beat rhythm.
- Medicines to treat depression e.g. imipramine and medicines used to quieten psychologically / mentally disturbed patients (e.g. chlorpromazine).
- Stimulent laxatives (e.g. bisacodyl and senna).

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine as it contains sucrose and lactose.

How to take
For oral use.

Adults: One tablet to be taken daily in the morning.

Children: Not recommended for use in children.

If you take more tablets than you should:
If you have taken more tablets than you should speak to your doctor or pharmacist straight away.

If you forget to take a dose of Indapamide Tablets:
If you forget to take a tablet for one or more days take another as soon as you remember and continue as prescribed. Do not take a double dose to make up for forgotten individual doses.

Possible side effects:
Like all medicines, indapamide may sometimes cause side effects. Those which may occur are:
- Low levels of sodium and potassium in the blood. Also loss of chloride which may affect the acid base balance of the body.
- A reduced circulating blood volume which may result in dehydration and dizziness and light-headedness that occurs when standing up after sitting or lying down.
- Increased levels of glucose and uric acid in the blood which may mean this medicine is not suitable for those with diabetes or gout.
- Liver problems.
- Allergic reactions usually affecting the skin.
- Skin rashes, itching, peeling or blistering of the skin.
- Possible worsening of pre-existing acute disseminated lupus erythematosus (rare, widespread inflammatory disease).

The following side effects that very rarely occur include:
- Blood cell disorders.
- Excess calcium in the blood.
- Nausea, constipation, dry mouth.
- Headache.
- Pancreatitis (symptoms may include severe abdominal pain moving to the back, fever, loss of appetite, nausea and vomiting).
- Pins and needles, muscle cramps.
- Dizziness, vertigo, fainting, fatigue.

If you experience any of the above or you notice anything unusual contact your doctor or pharmacist.

Storing the tablets
Keep out of the reach and sight of children.
Do not store above 25°C. Keep the container tightly closed/Store in the original package (blister) in order to protect the tablets from light and moisture.
Do not use the tablets after the expiry date shown on the label.
If you have any tablets remaining after your doctor tells you to stop taking them, return them to your pharmacist for safe disposal.

This leaflet was prepared September 2005

Co-pharma

Labelling

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

Product: Indapamide Label 2.5mg 100 Tabs.s
Item Code:
Colours used:

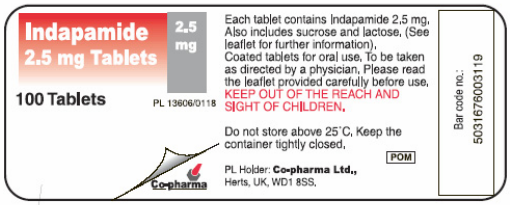
Dimensions: 85mm x 33mm

Red PMS 185
Black

Date: 16/ 2 / 2006

Approved by:

Proof: 3



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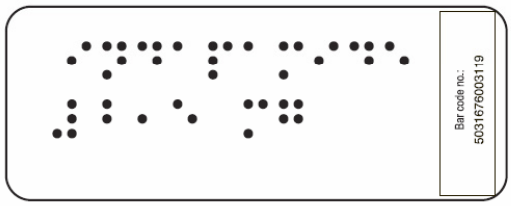

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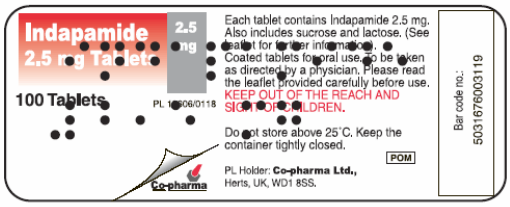

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

Product: Indapamide Carton 2.5mg 28Tabs.s
Item Code:
Colours used:

Red PMS 185
Black

Dimensions: 100mm x 21mm x 58mm

Date: 09/ 3 / 2006

Approved by:

Proof: 3

INDAPAMIDE 2.5MG TABLETS

PL 13606/0118

Product: Indapamide Carton 2.5mg 28Tabs.s
Item Code:
Colours used:

Red PMS 185
Black

Dimensions: 100mm x 21mm x 58mm

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Proof: 3