Tasagyl IV – Metronidazole 500mg in 100ml Solution for Infusion

Active Ingredient
Metronidazole

1 Name of the medicinal product
Metronidazole 500mg in 100ml Solution for Intravenous Infusion

2 Qualitative and quantitative composition
Metronidazole 5 mg/ml
100 ml of solution for infusion containing 500 mg of Metronidazole.

3 Pharmaceutical form
Solution for infusion
A clear, almost colourless to yellow solution.

4 Clinical particulars
4.1 Therapeutic indications
Metronidazole 500mg/100ml Intravenous Infusion is indicated in adults and children when oral medication is not possible for the following indications:

- The prophylaxis of postoperative infections due to sensitive anaerobic bacteria particularly species of Bacteroides and anaerobic Streptococci, during abdominal, gynaecological gastrointestinal or colorectal surgery which carries a high risk of occurrence of this type of infection. The solution may also be used in combination with an antibiotic active against aerobic bacteria.

- The treatment of severe intraabdominal and gynaecological infections in which sensitive anaerobic bacteria particularly Bacteriodes and anaerobic Streptococci have been identified or are suspected to be the cause.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration
Method of Administration
Metronidazole 500mg/100ml Intravenous Infusion should be infused intravenously at an approximate rate of 5ml/minute (or one bag infused over 20 to 60 minutes). Oral medication should be substituted as soon as feasible.

Indication	**Dosage**

Prophylaxis against postoperative infections caused by anaerobic bacteria	Primarily in the context of abdominal, (especially colorectal) and gynaecological surgery. Antibiotic prophylaxis duration should be short, mostly limited to the postoperative period (24 hours but never more than 48 hours). *Adults*: Intra-venous injection of single dose of 1000mg-1500mg, 30-60 minutes preoperatively or alternatively 500mg immediately before, during or after operation, then 500mg 8 hourly. *Children < 12 years*: 20-30mg/kg as a single dose given 1-2 hours before surgery. *Newborns with a gestation age <40 weeks*: 10 mg/kg body weight as a single dose before operation.
Anaerobic infections	Intravenous route is to be used initially if patient symptoms preclude oral therapy. Various schedules are possible. *Adults*: 1000mg – 1500mg daily as a single dose or alternatively 500mg every 8 hours. *Children > 8 weeks to 12 years of age*: The usual daily dose is 20-30mg/kg/day as a single dose or divided into 7.5 mg/kg every 8 hours. The daily dose may be increased to 40 mg/kg, depending on the severity of the infection. Duration of treatment is usually 7 days. *Children < 8 weeks of age*: 15mg/kg as a single dose daily or divided into 7.5mg/kg every 12 hours. *In newborns with a gestation age < 40 weeks*, accumulation of metronidazole can occur during the first week of life, therefore the concentrations of metronidazole in serum should preferably be monitored after a few days of therapy. Oral medication could be given, at the same dose regimen. Oral medication should be substituted as soon as feasible. *Duration of Treatment* Treatment for seven to ten days should be satisfactory for most patients but, depending upon clinical and bacteriological assessments, the physician might decide to prolong treatment e.g.; for the eradication of infection from sites which cannot be drained or are liable to endogenous recontamination by anaerobic pathogens from the gut, oropharynx or genital tract
Bacterial vaginosis	*Adolescents*: 400mg twice daily for 5-7 days or 2000mg as a single dose
Urogenital trichomoniasis	*Adults and adolescents*: 2000mg as a single dose or 200mg 3 times daily for 7 days or 400mg twice daily for 5-7 days *Children < 10 years*: 40mg/kg orally as a single dose or 15 – 30mg/kg/day divided in 2-3 doses for 7days; not to exceed 2000mg/dose
Giardiasis	*> 10 years*: 2000mg once daily for 3 days, or 400mg three times daily for 5 days, or 500mg twice daily for 7 to 10 days *Children 7 to 10 years*: 1000mg once daily for 3 days *Children 3 to 7 years*: 600mg to 800mg once daily for 3 days *Children 1 to 3 years*: 500mg once daily for 3 days

	Alternatively, as expressed in mg per kg of body weight: 15-40mg/kg/day divided in 2-3 doses.
Indication	**Dosage**
Amoebiasis	*> 10 years*: 400mg to 800mg 3 times daily for 5-10 days *Children 7 to 10 years*: 200mg to 400mg 3 times daily for 5-10 days *Children 3 to 7 years*: 100mg to 200mg 4 times daily for 5-10 days *Children 1 to 3 years*: 100mg to 200mg 3 times daily for 5-10 days Alternatively, doses may be expressed by body weight 35 to 50mg/kg daily in 3 divided doses for 5 to 10 days, not to exceed 2400mg/day
Eradication of Helicobacter pylori in paediatric patients	As a part of a combination therapy, 20mg/kg/day not to exceed 500mg twice daily for 7-14 days. Official guidelines should be consulted before initiating therapy

Elderly Population

Caution is advised in the elderly, particularly at high doses, although there is limited information available on modification of dosage.

Patients with renal failure

Routine adjustments of the dosage of Metronidazole are not considered necessary in the presence of renal failure.

No routine adjustment in the dosage of Metronidazole needs to be made in patients with renal failure undergoing intermittent peritoneal dialysis (IDP) or continuous ambulatory peritoneal dialysis (CAPD). However dosage reduction may be necessary when excessive concentrations of metabolites are found. In patients undergoing haemodialysis, Metronidazole should be re-administered immediately after haemodialysis

Patients with advanced hepatic insufficiency

In patients with advanced hepatic insufficiency a dosage reduction with serum level monitoring is necessary.

4.3 Contraindications

Hypersensitivity to the active substance, to other imidazole derivatives or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Liver disease:

Caution is needed in patients with severe hepatic impairment. The dose of metronidazole should be reduced as necessary. Metronidazole is mainly metabolised by hepatic oxidation. Substantial impairment of Metronidazole clearance may occur in the presence of advanced hepatic insufficiency. The risk/benefit ratio

of using Metronidazole to treat trichomoniasis in such patients should be carefully considered (for dosage adjustment see section 4.2). Plasma levels of Metronidazole should be closely monitored.

Caution is needed in patients with hepatic encephalopathy. Patients with severe hepatic encephalopathy metabolize metronidazole slowly, with resultant accumulation of metronidazole. This may cause exacerbation of CNS adverse effects. The dose of metronidazole should be reduced as necessary.

Cases of severe hepatotoxicity/acute hepatic failure, including cases with a fatal outcome with very rapid onset after treatment initiation in patients with Cockayne syndrome have been reported with products containing metronidazole for systemic use. In this population, metronidazole should therefore be used after careful benefit-risk assessment and only if no alternative treatment is available. Liver function tests must be performed just prior to the start of therapy, throughout and after end of treatment until liver function is within normal ranges, or until the baseline values are reached. If the liver function tests become markedly elevated during treatment, the drug should be discontinued.

Patients with Cockayne syndrome should be advised to immediately report any symptoms of potential liver injury to their physician and stop taking metronidazole.

Active Central Nervous System disease:
Metronidazole should be used with caution in patients with active disease of the Peripheral and Central Nervous System. Severe neurological disturbances (including seizures and peripheral and optic neuropathies) have been reported in patients treated with metronidazole. Stop metronidazole treatment if any abnormal neurologic symptoms occur such as ataxia, dizziness, confusion or any other CNS adverse reaction. The risk of aggravation of the neurological state should be considered in patients with fixed or progressive paraesthesia, epilepsy and active disease of the central nervous system except for brain abscess.

Encephalopathy has been reported in association with cerebellar toxicity characterized by ataxia, dizziness, dysarthria, and accompanied by CNS lesions seen on magnetic resonance imaging (MRI). CNS symptoms and CNS lesions, are generally reversible within days to weeks upon discontinuation of metronidazole. Aseptic meningitis can occur with metronidazole. Symptoms can start within hours of dose administration and generally resolve after metronidazole therapy is discontinued (see section 4.8).

Blood Dyscrasias
Metronidazole should be used with caution in patients with evidence or history of blood dyscrasia as agranulocytosis, leukopenia and neutropenia have been observed following metronidazole administration.

Renal Disease:
Metronidazole is removed during haemodialysis and should be administered after the procedure is finished. Patients with renal impairment, including patients receiving peritoneal dialysis, should be monitored for signs of toxicity due to the potential accumulation of toxic metronidazole metabolites.

Sodium restricted patients:
This medicinal product contains 13.5 mmol (310 mg) sodium per 100 ml. To be taken into consideration by patients on a controlled sodium diet.

Alcohol:

Patients should be advised to discontinue consumption of alcoholic beverages or alcohol-containing products before, during, and up to 72hours after taking metronidazole because of a disulfram-like effect (abdominal cramps, nausea, headaches, flushing, vomiting and tachycardia). See section 4.5.

Intensive or prolonged Metronidazole therapy:
As a rule, the usual duration of therapy with i.v Metronidazole or other imidazole derivatives is usually less than 10 days. This period may only be exceeded in individual cases after a very strict benefit-risk assessment. Only in the rarest possible case should the treatment be repeated. Limiting the duration of treatment is necessary because damage to human germ cells cannot be excluded.
Intensive or prolonged Metronidazole therapy should be conducted only under conditions of close surveillance for clinical and biological effects and under specialist direction. If prolonged therapy is required, the physician should bear in mind the possibility of peripheral neuropathy or leucopenia. Both effects are usually reversible. In case of prolonged treatment, occurrence of undesirable effects such as paraesthesia, ataxia, dizziness and convulsive crises should be checked. High dose regimes have been associated with transient epileptiform seizures.

Monitoring:
Due to increased risk for adverse reactions, regular clinical and laboratory monitoring (including blood count) are advised in cases of high-dose, prolonged or repeated treatment, in case of antecedents of blood dyscrasia, in case of severe infection and in severe hepatic insufficiency.

General:
Patients should be warned that Metronidazole may darken urine (due to Metronidazole metabolite).

4.5 Interaction with other medicinal products and other forms of interaction

Not recommended concomitant therapy:
Disulfiram: Concurrent use of metronidazole and disulfiram may result in psychotic reactions and confusion. Metronidazole should not be given to patients who have taken disulfiram within the last two weeks.
Alcohol: Disulfiram-like effect (warmth, redness, vomiting, tachycardia).
Alcohol beverage and drugs containing alcohol should be avoided. Patients should be advised not to take alcohol during Metronidazole therapy and at least 72 hours afterwards because of a disulfram-like (antabuse effect) reaction (flushing, vomiting, tachycardia).

Concomitant therapy requiring special precautions:
Oral anticoagulants (warfarin): metronidazole may increase the anticoagulant effects of warfarin and other oral anticoagulants, resulting in a prolongation of the prothrombin time and increased risk of haemorrhage (decrease in its liver catabolism). Patients taking metronidazole and warfarin or other oral coumarins concomitantly should have their prothrombin time and international normalized ratio (INR) monitored more frequently. Patients should be monitored for signs and symptoms of bleeding.

A large number of patients have been reported showing an increase in oral anticoagulant activity whilst receiving concomitant antibiotic therapy. The infectious and inflammatory status of the patient, together with their age and general well-being are all risk factors in this context. However, in these circumstances it is not clear as to the part played by the disease itself or its treatment in the occurrence of prothrombin time disorders. Some classes of antibiotics are more likely to result in this interaction, notably fluoroquinolones, macrolides, cyclines, cotrimoxazole and some cephalosporins.

Vecuronium (non depolarising curaremimetic): Metronidazole can potentialise the effects of vecuronium.

Combinations to be considered:
5 Fluoro-uracile: increase in the toxicity of 5 fluoro-uracile due to a decrease of its clearance.

Lithium: lithium retention accompanied by evidence of possible renal damage has been reported in patients treated simultaneously with lithium and Metronidazole. Lithium treatment should be tapered or withdrawn before administering Metronidazole. Plasma concentrations of lithium, creatinine and electrolytes should be monitored in patients under treatment with lithium while they receive Metronidazole.
Cholestyramine may delay or reduce the absorption of Metronidazole.

Phenytoin, barbiturates (phenobarbital): concomitant administration of drugs that induce microsomal liver enzyme activity, such as phenytoin or phenobarbital, may accelerate the elimination of metronidazole and therefore decrease its efficacy.

Cimetidine: concomitant administration of drugs that decrease microsomal liver enzyme activity, such as cimetidine, may cause decreased metabolism and reduced plasma clearance of metronidazole which may result in metronidazole toxicity.

Concomitant use of metronidazole and CYP3A4 substrates (e.g., amiodarone, tacrolimus, cyclosporine, carbamazepine, and quinidine) may increase respective CYP3A4-substrate plasma levels. Monitoring of plasma concentrations of CYP3A4 substrates may be necessary.

Busulfan: Plasma concentrations of busulfan may increase during concomitant treatment with metronidazole, which can result in serious busulfan toxicity such as sinusoidal obstruction syndrome, gastrointestinal mucositis, and hepatic veno-occlusive disease.

Laboratory tests:
Metronidazole may immobilise Treponema and thus may lead to falsely positive Nelson's test.
Metronidazole may interfere with serum aspartate transaminase (AST), alanine transaminase (ALT), lactate dehydrogenase (LDH), triglycerides, and glucose hexokinase determinations. Metronidazole causes an increase in ultraviolet absorbance at 340 nm resulting in falsely decreased values.

4.6 Fertility, pregnancy and lactation

Pregnancy
Metronidazole crosses the placental barrier.
Clinical data on a large number of exposed pregnancies and animal data did not show a teratogenic or fetotoxic effect. However unrestricted administration of nitroimidazolene to the mother may be associated with a carcinogenic or mutagenic risk for the unborn or new-born child.
Therefore, Metronidazole should not be given during pregnancy unless clearly necessary.

Lactation
Metronidazole is excreted in breast milk. During lactation either breast-feeding or Metronidazole should be discontinued.

Fertility

There are no clinical data relating to the effect of metronidazole on fertility.
Animal studies demonstrated adverse effects on the male reproductive system that are wholly or partially reversible after treatment withdrawal (see section 5.3).

4.7 Effects on ability to drive and use machines

No studies have been performed following intravenous treatment with Metronidazole on the ability to drive and use machines. Some adverse reactions to metronidazole such as seizure, dizziness, optic neuropathy, may impair the ability to drive or operate machines (see section 4.8).
Therefore, it is recommended that patients should not drive or use machines.

4.8 Undesirable effects

The following table of listed adverse reactions is derived from post-marketing data associated with Metronidazole.

Term	Frequency of occurrence
Very common	(≥1/10)
Common	(≥1/100 to <1/10)
Uncommon	(≥1/1 000 to <1/100)
Rare	(≥1/10 000 to <1/1 000)
Very rare	(<1/10 000)
Not known	(cannot be estimated from the available data)

System Organ Class	**Frequency**	**Undesirable effects**
Blood and Lymphatic System Disorders	Uncommon	Leukopenia
	Rare	Agranulocytosis, Pancytopenia, Neutropenia, Thrombocytopenia
	Not known	Eosinophilia
Immune System Disorder	Rare	Anaphylactic shock, Jarisch-Herxheimer reaction
	Not known	Hypersensitivity
Metabolism and Nutrition Disorders	Not known	Decreased appetite
	Rare	Hallucinations

Psychiatric Disorders	Not known	Depression, Confusional state, Insomnia
Nervous System Disorders	Common	Dysgeusia
	Uncommon	Headache
	Rare	Encephalopathy, Meningitis aseptic, Seizure, Somnolence, Neuropathy peripheral, Ataxia, Dizziness Dysarthria
	Not known	Hypoaesthesia, Paraesthesia, Dysgeusia
Eye Disorders	Rare	Optic neuropathy, Diplopia, Myopia
Cardiac Disorders	Not known	Tachycardia, Palpitations
Respiratory, Thoracic and Mediastinal Disorders	Not known	Dyspnoea
Gastrointestinal Disorders	Common	Glossitis, Stomatitis, Dry mouth
	Rare	Pancreatitis, Abdominal pain upper, Diarrhoea, Nausea, Vomiting
	Not known	Constipation, Tongue discoloration
Hepatobiliary disorders	Rare	Jaundice cholestatic
System Organ Class	**Frequency**	**Undesirable effects**
Skin and Subcutaneous Disorders	Rare	Stevens-Johnson syndrome, Toxic epidermal necrolysis, Angioedema, Erythema multiforme

	Not known	Pruritus, Swelling face, Urticaria, Hyperhidrosis, Rash
Musculoskeletal and Connective Tissue Disorders	Common	Myalgia
	Not known	Muscle spasms, Arthralgia
Renal and urinary disorders	Rare	Chromaturia
	Not known	Dysuria
General and Administration Site Conditions	Uncommon	Asthenia
	Rare	Mucosal inflammation, Pyrexia
	Not known	Injection site reaction, Malaise, Face oedema, Oedema peripheral, Chest pain, Chills
Investigations	Not known	Hepatic enzyme increased

4.9 Overdose

Symptoms

In cases of overdose in adults, the clinical symptoms are usually limited to nausea, vomiting and neurotoxic effects, including ataxia, slight disorientation, confusion, seizures and peripheral neurophathy.

Treatment

There is no specific treatment for Metronidazole overdose, Metronidazole infusion should be discontinued. Patients should be treated symptomatically.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use: imidazole derivatives
ATC Code: J01XD01 and
Pharmacotherapeutic group: Antiprotozoals: nitroimidazole derivatives ATC Code: P01AB01.

Metronidazole is an anti-infectious drug belonging to the pharmacotherapeutic group of nitroimidazole derivatives, which have effect mainly on strict anaerobes. This effect is probably caused by interaction with DNS and different metabolites.

Metronidazole has antibacterial and antiprotozoal actions and is effective against anaerobic bacteria and against Trichomonas vaginalis and other protozoa including Entamoeba histolytica and Giardia lamblia.

Anti-Microbial Spectrum:
The MIC breakpoints separating susceptible from intermediately susceptible and intermediately susceptible from resistant organisms are as following: - S ≤ 4 mg/l and R > 4 mg/l
The prevalence of acquired resistance may vary geographically and with time for selected species and local information is desirable, particularly when treating severe infections. This information gives only approximate guidance on probabilities whether microorganisms will be susceptible to Metronidazole or not.

Categories	
SUSCEPTIBLE	
Gram negative aerobes	*Clostridium perfringens*
Helicobacter pylori	*Eubacterium*
Anaerobes	*Fusobacterium*
Bacteroides fragilis	*Peptostreptococcus*
Bifidobacterium>>resistant (70%)	*Prevotella*
Bilophila	*Porphyromonas*
Clostridium	*Veillonella*
Clostridium difficile	
RESISTANT	
Gram positive aerobes	*Mobiluncus*
Actinomyces	*Propionibacterium acnes*
Anaerobes	
ANTIPARASITIC ACTIVITY	
Entamoeba histolytica	*Trichomonas vaginalis*
Giardia intestinalis	

Cross–resistance with tindazol occurs.

5.2 Pharmacokinetic properties

Distribution: After administration of a single 500 mg dose, mean Metronidazole peak plasma concentrations of ca. 14 – 18 µg/ml are reached at the end of a 20-minute infusion. 2-hydroxy-metabolite peak plasma

concentrations of ca. 3 µg/ml are obtained after a 1 g single i.v. dose. Steady state Metronidazole plasma concentrations of about 17 and 13 µg/ml are reached after administration of Metronidazole every 8 or 12 hours, respectively.

Plasma protein binding is less than 10%, and the volume of distribution 1.1 ± 0.4 l/kg.
Metabolism: Metronidazole is metabolised in the liver by hydroxylation, oxidation and glucuronidation. The major metabolites are a 2-hydroxy- and an acetic acid metabolite.

Elimination: More than 50% of the administered dose is excreted in the urine, as unchanged Metronidazole (ca. 20% of the dose) and its metabolites. About 20% of the dose is excreted with faeces. Clearance is 1.3 ± 0.3 ml/min/kg, while renal clearance is about 0.15 ml/min/kg. The plasma elimination half-life of Metronidazole is ca. 8 hours, and of the 2-hydroxy-metabolite ca. 10 hours.
Special patient groups: The plasma elimination half-life of Metronidazole is not influenced by renal impairment, however this may be increased for 2-hydroxy- and an acetic acid metabolite. In the case of haemodialysis, Metronidazole is rapidly excreted and the plasma elimination half-life is decreased to ca. 2.5 h. Peritoneal dialysis does not appear to affect the elimination of Metronidazole or its metabolites compared to patients with renal impairment.

In patients with impaired liver function, the metabolism of Metronidazole is expected to decrease, leading to an increase in the plasma elimination half-life. In patients with severe liver impairment, clearance may be decreased up to ca. 65%, resulting in an accumulation of Metronidazole in the body.

5.3 Preclinical safety data

Metronidazole has been shown to be non-mutagenic in mammalian cells *in vitro* and *in vivo*.

Metronidazole and a metabolite have been shown to be mutagenic is some tests with non-mammalian cells. Although Metronidazole has been shown to be carcinogenic in certain species of mice, it was not carcinogenic in either rats or guinea pigs. There is no suspicion of carcinogenicity in man.

Daily peroral metronidazole at 5-times the maximum human daily dose for greater than 4 weeks caused testicular toxicity and infertility in male rats. Fertility was restored in most subjects by 8 weeks after cessation of treatment, whereas the lower testicular and epididymal weights and sperm counts had improved but were still observed.

Daily peroral metronidazole at approximately 6-times the maximum human daily dose for ≥2 weeks caused testicular toxicity in male mice. Most indices of testicular toxicity were restored within 2 months after cessation of treatment, whereas the lower testicular and epididymal weights had improved but were still observed.

These studies demonstrate that the adverse effects of metronidazole on the male reproductive system are wholly or partially reversible after treatment withdrawal (see section 4.6).

6 Pharmaceutical particulars

6.1 List of excipients Disodium
phosphate dihydrate
Citric acid monohydrate

Sodium chloride
Water for Injections

6.2 Incompatibilities

Do not use equipment containing aluminium (e.g., needles, cannulae) that would come in contact with the drug solution as precipitates may form.

Metronidazole is incompatible with (includes but is not limited to):
- Aztreonam
- Cefamandole nafate
- Cefoxitin
- Penicillin G

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal product except for those mentioned in 6.6.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not remove unit from over-pouch until ready for use.

6.5 Nature and contents of container

Polyolefin/ Styrene-block co-polymer-based film bag, provided with a Single Function Connector System (SFC) assembly, comprising of polypropylene port and a polypropylene cap assembled with rubber disc.
Sealed with triple laminated over-pouch.
The bag size is 100ml.
Outer carton contents: 10 bags of 100ml, 20 bags of 100ml. Not all pack sizes are marketed.

6.6 Special precautions for disposal and other handling

Use only if the solution is clear, without visible particles and if the container is undamaged. Administer immediately following the insertion of infusion set.
Do not remove unit from over-pouch until ready for use.
The inner bag maintains the sterility of the product.
Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is completed.
Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration.
Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers.
The solution should be administered with sterile equipment using an aseptic technique. The equipment should be primed with the solution in order to prevent air entering the system.

In patients maintained on intravenous fluids, Metronidazole 500mg/100ml Intravenous Infusion may be diluted with appropriate volumes of 0.9% sodium chloride solution, dextrose 5% - 0.9% sodium chloride solution, dextrose 5% w/v or potassium chloride infusions (20 and 40 mmol/litre).
Using an incorrect administration technique might cause the appearance of fever reactions due to the possible introduction of pyrogens. In the case of adverse reaction, infusion must be stopped immediately.
Additives:
Additives known or determined to be incompatible should not be used.
Before adding a substance or medication, verify that it is soluble and stable in metronidazole, and that the pH range of metronidazole is appropriate. Additives may be incompatible. When introducing additives, the instructions for use of the medication to be added and other relevant literature must be consulted (see Section 6.2).
Mix the solution thoroughly when additives have been introduced.
After addition, if there is a colour change and/or the appearance of precipitates, insoluble complexes or crystals, do not use.
Do not store solutions containing additives.
The product should be used immediately after opening.
Discard after single use.
Discard any unused portion.
Do not reconnect partially used bags.

7 Marketing authorisation holder

Tasa Pharma Limited
Unit C1-C3
Kay complex
Nairobi
Kenya