

Abbott Laboratories Limited

Queenborough
Kent ME11 5EL



ABBOCIN*

Presentation Each yellow, sugar-coated tablet contains 250 mg Oxytetracycline Dihydrate BP.

Uses Organisms sensitive to oxytetracycline include a large number of Gram-negative and Gram-positive pathogenic bacteria. Those organisms that are sensitive to tetracycline in the concentrations usually achieved in the body during treatment are *Bacillus anthracis*, *bordetella* spp., *brucella* spp., *Escherichia coli*, *haemophilus* spp., *klebsiella* spp., *Proteus vulgaris*, *staphylococci*, *streptococci*, *mycoplasma*, *Entamoeba histolytica*, *Trichomonas vaginalis*, certain rickettsias and larger viruses. *Pseudomonas aeruginosa*, *salmonella* spp. and *Mycobacterium tuberculosis* are less susceptible.

Dosage and administration For adults and older children the dose is 250 mg four times daily taken orally. In severe infections this dose may be doubled or trebled.

Contra-indications, warnings, etc

Contra-indications: Hypersensitivity to the tetracyclines.

Precautions and side-effects: As with other tetracyclines Abboцин should be administered with great care to individuals with renal or hepatic dysfunction. Because of the staining of teeth and effects on bone development, tetracyclines should not be given in pregnancy, or to children under 12 years of age. Tetracyclines should not be administered simultaneously with milk, antacids, or preparations containing iron, calcium or magnesium.

Side-effects include nausea, diarrhoea, and symptoms resulting from the overgrowth of non-susceptible organisms. Overgrowth of *Candida albicans* in the mouth may cause glossitis and stomatitis which may extend into the trachea and bronchi; overgrowth of *C. albicans* in the bowel results in pruritis ani; overgrowth of resistant coliform organisms such as *pseudomonas* and *proteus* may also cause diarrhoea. Occasionally resistant staphylococci may give rise to a fulminating enterocolitis. Allergic reactions and skin rashes are rare.

Pharmaceutical precautions Store below 25°C. Keep container tightly closed.

Legal category POM.

Package quantities Abboцин is supplied in Securitainers of 1,000 sugar-coated tablets (List No. C945).

Further information Available carbohydrate content approx. 0.29 g.

Product licence number 0549/5088.

AKINETON*

Presentation Akineton is supplied in white scored tablets, with a triangle on the opposite side, containing 2 mg biperiden hydrochloride. Also available in 1 ml ampoules containing 5 mg of biperiden lactate.

Uses In drug-induced extrapyramidal symptoms and all other types of parkinsonism. It is particularly effective against rigidity.

Dosage and administration 1. **Oral:** The initial oral dose is 1 mg twice daily ($\frac{1}{2}$ tablet) which is increased gradually to 2 mg (1 tablet) three times daily during or after meals. After several days the dose may be increased further according to the patient's response. The optimum maintenance dosage varies from 3 mg to 12 mg daily.

Note. When salivation is reduced the tablets are best taken after meals; in other cases, they should be taken during meals.

2. **Parenteral injection:** In severe cases, Akineton may be given by intramuscular or slow intravenous injection in divided doses, totalling 5–20 mg of the lactate daily.

Note. With parenteral administration, the systolic blood pressure may be decreased by 20–30 mm Hg and the diastolic by 5–20 mm Hg.

3. **Combined treatment:** In some cases the response of tremor to the drug may be inadequate. In such cases combined therapy with a preparation effective against tremor should be considered. However, it is advisable to continue with Akineton alone until it has been established that its effect on tremor is inadequate.

4. **Reversal effect:** An increase in parkinsonism symptoms during treatment is a preliminary sign of intoxication due to excessive dosage and should be treated by reduction of the dose.

Contra-indications, warnings, etc

Contra-indications: Sensitivity to Akineton (Biperiden hydrochloride). Glaucoma. Intestinal obstruction.

Precautions: Care should be taken when administering Akineton to epileptics and patients with cardiac arrhythmias. Patients with recent myocardial infarction should be given Akineton only if the heart rate is well controlled.

Occasionally drowsiness may occur, and patients who drive a car or operate any other potentially dangerous machinery which requires concentration should be warned that side-effects of this type are a possibility. As with other drugs acting on the central nervous system, the consumption of alcohol should be avoided during Akineton therapy.

As with every other long-term medication regular blood counts are recommended.

Treatment with Akineton should not be discontinued abruptly. Transfer of patients to Akineton from other anti-parkinsonism agents should be made gradually, the original agent being reduced in dose as Akineton is substituted.

Usage during pregnancy: The potential benefits of Akineton therapy should be weighed against possible hazards to the patient as well as to the foetus. No data are available regarding continuous administration in pregnant patients.

Side-effects: Akineton is well tolerated and side-effects are minimal even with prolonged usage. Dryness of the mouth, disturbances of accommodation, fatigue

Administration: A cleansing enema is rarely required prior to the administration of Pentothal Suspension. The small volume to be administered usually does not induce defaecation and, therefore, buttock strapping is not required.

However, if for any reason a cleansing enema is indicated, it should consist of tapwater rather than soapsuds, and should be given at least six hours before the administration of Pentothal. If atropine or similar pre-medication is given, it should be administered about one hour before Pentothal. Before insertion, one of the applicators should be attached to the Abbo-Sert syringe and the plunger advanced, so as to fill the nozzle with the suspension. The tip of the nozzle may be lubricated with any suitable agent, and should then be gently inserted into the rectum. The required amount of suspension is injected (using the calibration on the Abbo-Sert syringe) and the nozzle is withdrawn and discarded.

Contra-indications, warnings, etc

Contra-indications: Severe respiratory embarrassment, marked renal or hepatic insufficiency, advanced cardiac disease, and hypersensitivity to the barbiturates.

Precautions and side-effects: The suspension is not recommended for patients who are to undergo rectal surgery, or for patients suffering from inflammatory or neoplastic lesions of the lower bowel. Rectal irritation may occur rarely. The suspension must never be administered unless the patient can be kept under continuous observation and resuscitative equipment is readily available. Do not use excessive force on the plunger.

Overdosage: It is generally agreed that respiratory depression or arrest due to unusual sensitivity to thiopentone, or overdosage, is easily managed if there is no concomitant respiratory obstruction. If the airway is patent, any method of ventilating the lungs (that prevents hypoxia) will be successful in maintaining other vital functions. Since depression of respiratory activity is one of the characteristic actions of Pentothal, it is important to observe respiration closely.

Pharmaceutical precautions Pentothal Abbo-Sert does not require refrigeration but should be stored at normal room temperature, preferably in a cool dry place.

Legal category POM.

Package quantities Pentothal Abbo-Sert is supplied singly (List No. 7236).

Further information Nil.

Product licence number 0037/5067.

PROFILATE* ▼

Presentation Profilate is a stable, dried concentrate of Human, Anti-Haemophilic Factor (Factor VIII AHF, AHG). It is in the form of a white, lyophilised powder for reconstitution, with Water for Injection USP. The total AHF activity, expressed in International Units, is given on the label of each vial. One International Unit is defined as the activity present in 1 ml of fresh pooled human plasma used.

Uses In the therapy of haemophilia A (classical haemophilia) Profilate is effective in arresting bleeding due to deficiency of Factor VIII and restoring the levels of this factor to normal or near normal values without overloading the circulatory system.

Dosage and administration Reconstitution:

1. Warm the Profilate and the diluent vials to room temperature (not above 37°C).

2. Remove the aluminium seal and dust cap from the vial containing Water for Injection USP.

3. Swab the exposed rubber surface with alcohol (remove any excess).

4. Remove all covering from one end of the double-ended needle supplied, and insert this exposed end through the bung into the vial.

5. Remove aluminium band and dust cap from the Profilate vial. Tap the vial gently to dislodge concentrate from the sides.

6. Swab the exposed rubber surface with alcohol (remove any excess).

7. Remove the plastic cap from the upper end of the double-ended needle seated in the water for injection vial. Hold the Profilate vial in one hand and invert the vial containing the water for injection in the other. Push the exposed end of the needle through the bung in the Profilate vial. Make certain that the water for injection vial is always above the one containing Profilate. There should be enough vacuum in the vial to draw in all the water for injection.

8. Disconnect the two vials by removing the needle from the Profilate vial. Shake vigorously for ten seconds, then agitate or rotate the Profilate vial until all the powder is dissolved. Reconstitution usually takes between five and ten minutes.

Administration: Profilate should be administered intravenously not more than three hours after reconstitution. It may be given slowly as a single intravenous injection or by infusion. It should not be administered at a rate exceeding 10 ml per minute. Rapid administration may result in vasomotor reactions.

a) By syringe: 1. Using aseptic technique, attach the filter needle to a sterile disposable plastic syringe and insert the filter needle into the reconstituted concentrate vial. Inject air and aspirate the concentrate from the vial into the syringe.

2. Remove and discard the filter needle from the syringe and attach it to a 21G Butterfly Infusion Set, make a venipuncture and administer slowly.

Note. If more than one vial of Profilate is to be administered only a single venipuncture will be required if a Butterfly Infusion Set is used.

b) By infusion set: 1. Close the clamp on the infusion set.

2. With the vial upright thrust the piercing point straight through the bung. Do not twist or angle.

3. Immediately invert the vial to establish automatically the proper fluid level in the drip chamber (half full).

4. Attach the 21 G Butterfly Infusion Set, open the clamp and allow the solution to expel air from the tubing and needle. Close the clamp.

5. Make a venipuncture and adjust the flow.

Note. Discard all administration equipment after use.

Dosage: The formulae given below provide a guide to dosage calculations:

Number of AHF units required	Body weight = in kg	Desired increase in Factor VIII percentage
		$\times 44 \times$

OR

Number of AHF units required	Body weight = in lb	Desired increase in Factor VIII percentage
		$\times 20 \times$

Mild to moderate haemorrhages may be treated usually with a single administration sufficient to raise the plasma AHF level to 20–30%. In the event of more serious haemorrhage the patient's plasma AHF level should be raised to 30–50%. Infusions are generally

required twice daily for several days. In surgical patients with Factor VIII deficiency the level must be raised to 50–80%, and maintained at, or above, 30% for approximately two weeks post-operatively. For dental extractions the AHF level should be raised to 50% immediately before the procedure; further Factor VIII may be given if bleeding recurs.

In patients with severe Factor VIII deficiency who experience frequent haemorrhages, Profilate may be administered prophylactically on a daily or every other day schedule, so as to raise the AHF level to approximately 15%.

Contra-indications, warnings, etc

Contra-indications: There are no known contra-indications to the use of Profilate.

Warnings: Profilate is prepared from units of human plasma which have been tested by radioimmunoassay and found non-reactive for hepatitis B antigen (HB_sAg). However, the methods at present available are not sensitive enough to detect all units of potentially infective plasma, and the risk of transmitting hepatitis is still present. Patients with mild deficiencies who consequently have not received multiple transfusions of blood, or blood products, are at greatest risk. Under such circumstances the benefits of Profilate administration must be weighed carefully against the risk of viral hepatitis; single donor products are preferable whenever possible.

Precautions: About 5–8% of haemophilia A patients develop inhibitors to Factor VIII. Rarely, other patients acquire similar inhibitors. The management of patients with inhibitors requires careful monitoring, especially if surgical procedures are indicated. In patients with inhibitors, the response to Profilate may be much less than expected, and larger doses are often required. Patients with high inhibitor levels may not respond to Profilate at all.

Note. Nurses, and others who administer this material, should exercise appropriate caution because of the risk of exposure to viral hepatitis.

Side-effects: These include urticaria, fever, chills, nausea, vomiting, headache, somnolence and lethargy. Some patients frequently develop reactions of a mild nature following the administration of Profilate. Reactions may be of an allergic type, and if the patient requires additional Profilate a vial from a different batch should be administered.

Massive doses have given rise to acute anaemia, increased tendency to bleed or hyperfibrinogenaemia.

Pharmaceutical precautions Profilate should be stored at temperatures between 2°C and 8°C (36°F and 46°F).

Note. Discard any unused concentrate.

Legal category POM.

Package quantities Profilate is supplied for intravenous administration in a single-dose vial, together with a suitable volume of Water for Injection USP (usually 25 ml), a sterile double-ended reconstitution needle and a sterile filter needle (List No. 2042).

Further information When reconstituted sodium content not more than 0.20 mmol per ml.

Product licence number 0037/0071.

SELSUN*

Presentation Selsun is a 2.5% w/v suspension of selenium sulphide in a suitable detergent base.

Uses Selsun is indicated for:

1. The treatment of simple dandruff and seborrhoeic dermatitis of the scalp.
2. The treatment of tinea versicolor.

Dosage and administration Topical application only.

1. In the treatment of dandruff and seborrhoeic dermatitis, a liberal amount of Selsun should be applied twice a week for the first two weeks and then once a week for the next two weeks to keep the condition under control. After this initial course of treatment it should not be used more often than necessary.
2. In tinea versicolor, single overnight application to the infected areas is recommended.

Application: a) *Dandruff and seborrhoeic dermatitis* The scalp should be washed with soap and water to remove grease before Selsun is applied.

Note. Any toilet or other mild soap may be used but not a detergent shampoo. Shake well before use.

1. Apply a liberal amount of Selsun to a wet scalp. Wash the hair and scalp thoroughly. Avoid contact with eyes.

2. Allow lather to remain on scalp for two to three minutes.

3. Rinse the hair and scalp.

4. Apply more Selsun and repeat steps 1 and 2.

5. Rinse the hair and scalp thoroughly.

6. Wash hands thoroughly.

Although Selsun is yellowish-orange in colour, proper use does not discolour white or light-coloured hair. Patients with such hair should be advised to rinse thoroughly after treatment to avoid any possible colour remaining on the hair.

b) *Tinea versicolor*

1. Apply Selsun to the infected areas, allow to dry and leave overnight.

2. Wash off thoroughly with warm water in the morning.

Contra-indications, warnings, etc

Precautions and side-effects: Selsun should be very thoroughly rinsed from the hair before dyeing, tinting or waving the hair. It should not be applied for a period of two days before or after any of these procedures. The preparation should not be used until all traces of any ointment containing metallic compounds (e.g. mercuric ointments) have been removed from the scalp. Silver jewellery, hairpins, and other metal objects may discolour in contact with Selsun and should be removed if possible. Increased falling out of hair may occur with active treatment of any scalp condition. The hair, impoverished by the disease, becomes loosened in the hair follicles and there is a tendency for increased falling out to occur initially with treatment. It should be stressed that this hair loss is caused by the disease and not the treatment. Oiliness of the hair may increase following the use of Selsun. Hypersensitivity reactions are extremely rare. Although selenium sulphide is toxic if taken orally it is extremely insoluble and no serious toxic effects have been recorded following the ingestion of as much as 120 ml of the 2.5% suspension, at any one time. When applied externally as recommended, extensive testing has shown that absorption through the skin is negligible because of the insolubility of selenium sulphide.

Ingestion: Symptoms: Ingestion is usually followed by nausea and vomiting.

Treatment: Vomiting should be provoked or gastric lavage undertaken. General supportive measures are required. A purgative may be administered to hasten elimination.