



# Data Sheet Compendium 1974

# ABPI

## Data Sheet Compendium

### 1974

WELLBUTRIN	
Eli Lilly	
Wellbutrin	250
	100
	50
	25
	12.5
	6.25
	3.125



The Association of the British Pharmaceutical Industry  
162 Regent Street London W1R 6DD



# Armour Pharmaceutical Company Limited

Hampden Park  
Eastbourne  
Sussex BN22 9AG

## AAA\* MOUTH AND THROAT SPRAY

**Presentation** Each can contains 7.5 g with a metered valve providing 60 x 100 mg doses.

Benzocaine BP 1.5% w/w  
Cetalkonium chloride 0.0413% w/w

in an inert flavoured propellant.

**Uses** Treatment of sore throats caused by cold, post-nasal drip and other irritants, and minor infections of the mouth and throat.

**Dosage and administration** *Adults:* 2 shots every two to three hours if required (not more than 16 shots in 24 hours or as directed by the physician).

*Children aged 6-12:* 1 shot every two to three hours if required (not more than 8 shots in 24 hours or as directed by the physician).

### Contra-indications, warnings, etc

**Side-effects:** Hypersensitivity reactions to benzocaine have been reported.

**Precautions:** Avoid spraying into eyes.

Contents under pressure – do not puncture.

Keep away from heat and flames – do not throw finished container into fire.

**Contra-indications:** None known.

**Pharmaceutical precautions** Store in cool place. Indefinite shelf-life.

**Legal category** P1.

**Package quantities** Each can contains 7.5 g with a metered valve providing 60 x 100 mg doses (shots).

**Further information** Published clinical studies have demonstrated antibacterial activity by the reduction in the population of pathogenic organisms of the buccal mucosa. Together with its local anaesthetic activity, this has been found of value in the treatment of pain and infection following tonsillectomy.

**Product licence number** 0231/5026.

## ACTHAR\* GEL ACTHAR\*

**Presentation** *Acthar Gel:* Corticotrophin Gelatin Injection BP in vials containing 20, 40 and 80 i.u./ml for subcutaneous or intramuscular use.

*Acthar:* Corticotrophin Injection BP in vials containing 25 and 40 i.u. as a lyophilised powder.

**Uses** Acute and chronic asthma (not status asthmaticus). Rheumatoid arthritis. Still's disease (juvenile chronic polyarthritis). Inflammatory disease of the colon (ulcerative colitis). Bell's palsy. Retrobulbar neuritis.

**Dosage and administration** *Rheumatoid arthritis and asthma:* The aim is to obtain a satisfactory therapeutic effect with minimal dosage. The initial dose, however, will vary depending on the severity of the condition, and the clinical response is the sole

measure of adequate dosage. Therapeutic effects may appear within hours, though chronic diseases may not show improvement for several days.

Because adrenals vary in their sensitivity to ACTH and because disease conditions vary in their response to corticosteroids, no specific uniform dose can be equally effective for all individuals. Once the disease is under control, the total daily dose should be decreased as rapidly as possible. Dosage reduction should be consistent with maintaining clinical improvement. Each dosage level should be maintained for three to seven days before attempting a further reduction.

When the smallest daily maintenance dose is established, attempts should be made to lengthen the dosage intervals. If at any step of dosage reduction symptoms reappear, a return to the previous effective schedule is necessary before another attempt at dosage reduction is made. Often, however, Acthar Gel can be completely withdrawn as the patient will experience a remission. Should the disease process become active again, then another course of Acthar Gel may be given. If the disease is of such a nature as to require maintenance therapy, the smallest effective dose at the greatest intervals should be determined. Less than full suppression of disease symptoms is recommended when the doses needed for full relief produce significant side-effects.

It may be more convenient and is therapeutically equally effective to adhere to a fixed unit dosage – say 40 units per injection – and to extend the interval between injection (once or twice weekly) instead of reducing the unit dose and adhering to daily injections.

**Acute exacerbation of asthma** (not status asthmaticus): 200 i.u. Acthar Gel repeated at a 72-hour interval gives remission in the majority of cases. Maintenance therapy may be Acthar Gel 80 i.u. every two to three days or bronchodilator therapy as necessary.

**Still's disease:** 40 i.u. Acthar Gel daily for three days, reducing to 20 i.u. daily and then 20–40 i.u. on alternate days. Suppression of symptomatology without the appearance of 'cushingoid signs' is the aim of therapy.

The administration of ACTH to children should be confined to early morning (approximately 10 am) to reduce the incidence of growth interference.

**Bell's palsy:** Treatment should commence as soon as possible after the onset of paralysis.

80 i.u. Acthar Gel daily for five days, reducing to 60 i.u. on day 6, 40 i.u. on day 7, 20 i.u. on day 8 and 10 i.u. daily on days 9 and 10.

Alternatively a simplified regimen of 40 i.u. daily for 10 days, or until signs of improvement occur, can be employed.

**Retrobulbar neuritis:** 40 i.u. Acthar Gel daily for a period of 30 days.

**Inflammatory disease of the colon:** 80 i.u. Acthar Gel



**Bayer Pharmaceuticals Limited**  
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Sussex RH16 1TP



**BAYCARON\***

**Presentation** White, round tablets, size 7 mm x 2 mm, each containing 25 mg mefruside.

**Uses** Mefruside is a diuretic agent and is intended for the treatment of hypertension and oedema.

**Dosage and administration** Mefruside is best taken with a little fluid as a single morning dose.

**Oedema:** Initially for 10–14 days, 25–50 mg every morning increasing if necessary to 75–100 mg to obtain the desired response. Daily doses in excess of 100 mg usually do not further increase diuresis.

For maintenance, and for long-term therapy, 25 mg each morning.

Alternate day dosage may also be used.

**Hypertension:** Initially for 10–14 days, 25–50 mg, then a maintenance dose of 25 mg each morning. Alternate day dosage may also be used.

**Contra-indications, warnings, etc**

**Contra-indications:** Severe hypokalaemia and hepatic coma.

**Side-effects:** Occasionally with daily doses up to 100 mg dyspepsia and nausea are encountered initially, but usually subside on continuing treatment.

**Overdosage:** There is no special antidote or other action to be taken, since an adverse reaction is unlikely.

**Precautions:** As with other diuretics, during long-term treatment with Mefruside potassium supplements may be necessary, especially for patients with impaired liver function, or for those also receiving cardiac glycosides. No teratogenic effect has been shown to be related to the use of Mefruside in animals or following its use in toxemia of pregnancy, but the benefits of the preparation should be weighed against the possible risks in the first trimester of pregnancy.

**Pharmaceutical precautions** There are no special precautions or requirements regarding the storage of Mefruside.

**Legal category** No legal restrictions on sale or supply, but the manufacturers recommend its supply on prescription only.

**Package quantities** Calendar pack of 56 tablets. Bottles of 150 tablets.

**Further information** Nil.

**Product licence number** 0010/5002.

**BAYOLIN\***

**Presentation** A white cream. Each 100 g cream contains heparinoid 'Bayer' 5,000 HDBu., glycolester of monosalicylic acid 10 g, benzyl nicotinate 2.5 g.

**Uses** Bayolin is a rubefacient used to treat all forms of muscular rheumatism, muscular stiffness due to exertion, lumbago, lumbar and cervical syndrome, local therapy of pains in muscles and joints due to

rheumatic polyarthritis, arthroses and spondylosis deformans.

**Dosage and administration** Topical application two or three times daily, the cream being massaged gently into the affected area until absorbed.

**Contra-indications, warnings, etc** **Side-effects:** Occasionally a skin reaction to the nicotinic acid component of Bayolin may be seen.

**Precautions:** Bayolin is very well tolerated, but like any other rubefacient it can be very painful if it is allowed to get into the eyes, or come into contact with mucous membranes. It is advisable for the hands to be washed after application.

**Pharmaceutical precautions** There are no special requirements for storage or other precautions to be taken.

**Legal category** No legal restrictions on sale or supply.

**Package quantities** Bayolin Cream is available in 35 g tubes.

**Further information** Nil.

**Product licence number** 0010/5001.

**CANESTEN\***

**Presentation** **Cream:** A white cream containing 1% Clotrimazole.

**Vaginal tablets:** White unmarked convex tablets measuring 25 mm x 10 mm, each containing 0.1 g Clotrimazole.

**Uses** Clotrimazole is a broad-spectrum antifungal and trichomonicide recommended for the treatment of:

**Cream:** 1. All dermatomycoses due to dermatophytes (e.g. Trichophyton species).

2. All dermatomycoses due to yeasts (Candida species).

3. All dermatomycoses due to moulds and other fungi.

4. Skin diseases showing secondary infection with these fungi, including: interdigital mycoses (e.g. athlete's foot), paronychias (also associated with nail mycoses), mycoses in skin folds, Candida vulvitis, Candida balanitis, pityriasis versicolor, erythrasma.

**Vaginal tablets:** Leucorrhoea, vulvo-vaginitis and vaginitis due to fungi – mainly Candida – and/or Trichomonas.

**Dosage and administration** **Cream:** Clotrimazole Cream should be thinly applied two to three times daily to the affected areas and rubbed in gently.

Treatment should be continued for at least one month from dermatophyte infections, pityriasis, erythrasma, and at least two weeks for Candida infections.

To prevent relapse, treatment should be continued