1101018701

Dysport®

Clostridium botulinum type A
toxin-haemagglutinin complex

Patient Information Leaflet

Information for the patient

Please read this leaflet carefully. It provides some information about this medicine. If there are any questions, please ask the doctor. The name of this medicine is Dysport. Its active ingredient is *Clostridium botulinum* type A toxin-haemagglutinin complex. Dysport also contains albumin and lactose, and is presented as a powder. For the injection, Dysport will be dissolved in Sodium Chloride for Injection.

Pack size

Each pack contains 1 vial of Dysport.

What is Dysport?

Dysport is a toxin produced by *Clostridium botulinum* bacteria. The toxin acts on the junctions between the nerves and muscles, preventing the release of one of the chemical messengers called acetylcholine from the nerve endings which would normally cause the muscle to contract. If the messenger is prevented from being released this results in a weakened muscle and helps to reduce some of the abnormal muscle contractions. Each vial of Dysport contains 500 units of the toxin complex. These units apply to Dysport only and are not the same for other medicines containing botulinum toxin.

Who makes Dysport?

Dysport is manufactured by:

Ipsen Biopharm Limited,
Ash Road, Wrexham Industrial Estate,
Wrexham LL13 9UF, UK.

The product licence holder is:

Ipsen Limited, 190 Bath Road, Slough,
Berkshire, SL1 3XE, UK.

What is Dysport used for?

Dysport is used to manage the symptoms of arm spasticity in adults, in conjunction with physiotherapy. Dysport is also used for the treatment of paediatric cerebral palsy spasticity, spasmodic torticollis, blepharospasm and hemifacial spasm. Arm spasticity is an increased stiffness in the arm muscles which develops in many patients after a stroke and can lead to restricted use of the arm. Paediatric cerebral palsy spasticity is a disorder in which some muscles become stiff and movement is difficult. Spasmodic torticollis is where there is turning movement of the neck leading to an unusual head and shoulder position. Blepharospasm is a condition affecting the eyelid muscles causing uncontrollable blinking and closure of the eyelids. Hemifacial spasm is a condition which causes the muscles on one side of the face to contract without control from the person affected.

Is there any reason for not being given Dysport?

You should not be given Dysport if you have had a previous allergic reaction to botulinum toxin or any of the ingredients.

Tell the doctor if:

- There is a change or worsening of symptoms.
- You think you are allergic to any of the ingredients contained in Dysport.
- You have had any unusual reactions such as skin rashes following any previous injection of toxin.
- You are taking any medicines, in particular aminoglycoside antibiotics.
- You have any history of bronchitis, pneumonia and problems with breathing.
- There have been any previous prolonged periods of muscle weakness.
- You have problems swallowing.
- You are pregnant or think you may be pregnant or you are breast feeding your baby.

Because there are increased risks of having toxin injections under these circumstances.

Additional information

Dysport contains a small amount of albumin which has been obtained from human blood.

The risk of a viral infection cannot be eliminated completely when using human blood or products made from human blood.

How will the medicine be given?

The doctor will make up the injection and give the injection.

The doctor will decide where to make the injections and for how long treatment is needed.

If being treated for arm spasticity, injections of Dysport will be given in a hospital or clinic which specialises in treating this condition. The doctor who injects the medicine will be specially trained and experienced in giving Dysport injections. The dose of Dysport given will not exceed 1000 units in total. The doctor may divide the amount between the affected arm muscles.

Data on repeated and long-term treatment are limited.

If being treated for paediatric cerebral palsy, injections of Dysport will be given in a hospital which specialises in treating this condition. The doctor will inject the medicine and he or she will be specially trained and experienced in giving Dysport injections. The first dose of Dysport will be 20 units/kg. The doctor will divide the amount between both calf muscles. If only one calf is affected by spasticity, the doctor will only give injections of 10 units/kg in this calf. Injections will be given approximately every 16 weeks.

If being treated for spasmodic torticollis, injections of Dysport will be given in a hospital which specialises in treating this condition. The doctor will inject the medicine and he or she will be specially trained and experienced in giving Dysport injections. The first dose of Dysport will be 500 units in total. The doctor will divide this amount into a number of places in the neck, probably into 2 or 3 of the neck muscles most affected by the condition. The doctor will decide how much to give and which muscles to inject. Injections will be given approximately every 12 weeks depending on how long before the relaxing effect on the muscle wears off. The doctor will decide when the next injection is needed and how much of the medicine will be injected.

If being treated for blepharospasm affecting both eyes, the first injection will be approximately 120 units per eye. The medicine will be injected just under the skin at certain sites around the eye, these sites and the exact amount needed will be decided by the doctor. Injections will be given approximately every 12 weeks when the relaxing effect on the muscles is wearing off. On the next visits the amount of Dysport given may be reduced to 80 or 60 units per eye. The doctor will decide what dose to administer. If only one eye is affected by blepharospasm, the doctor will only give injections of Dysport around this eye.

If being treated for hemifacial spasm the doctor will give injections as for blepharospasm but on the affected side only.

Dysport is not recommended for use in children in the treatment of arm spasticity, spasmodic torticollis, blepharospasm and hemifacial spasm.

Contact your doctor and seek medical attention immediately if you develop problems with swallowing, speech or breathing.

What shall I do if I miss an injection?

Nothing will happen if an injection is missed other than some of the spasm or muscle stiffness may return. Consult the doctor and he will decide when the next injection is needed.

What will happen if I stop taking Dysport?

The relaxing effect will eventually wear off and the muscle movements will return to the way they were before treatment.

What side effects can Dysport have?

Along with its desired effects Dysport may cause unwanted effects because of a weakening of muscles near the injected muscle.

General

The most common side effects are:

- A temporary change in the muscles near to where the injection was given.
- Bruising or swelling around the site where the injection was given or feel a burning sensation at the time the injection is given.
- Generalised weakness.
- Tiredness.
- Flu-like symptoms.

DETACH HERE AND GIVE INFORMATION TO PATIENT

Dysport®

Clostridium botulinum type A
toxin-haemagglutinin complex

INFORMATION FOR THE DOCTOR

1 NAME OF THE MEDICINAL PRODUCT

Dysport.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	Per Vial
Active Constituent	
Clostridium botulinum type A toxin-haemagglutinin complex	500U *
Other Constituents	
Albumin solution	125 MCG
Lactose	2.5 MG

* One unit (U) is defined as the median lethal intraperitoneal dose in mice.

3 PHARMACEUTICAL FORM

Injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dysport is indicated for focal spasticity, including the treatment of:

- arm symptoms associated with focal spasticity in conjunction with physiotherapy; and
- dynamic equinus foot deformity due to spasticity in ambulant paediatric cerebral palsy patients, two years of age or older, only in hospital specialist centres with appropriately trained personnel.

Dysport is also indicated for the following treatments:

- Spasmodic torticollis in adults
- Blepharospasm in adults
- Hemifacial spasm in adults

4.2 Posology and method of administration

The units of Dysport are specific to the preparation and are not interchangeable with other preparations of botulinum toxin.

Training: Dysport should only be administered by appropriately trained physicians.

Ipsen can facilitate training in administration of Dysport injections.

The exposed central portion of the rubber stopper should be cleaned with alcohol immediately prior to piercing the septum. A sterile 23 or 25 gauge needle should be used.

Arm spasticity:

Posology

The recommended dose is 1000 units in total, distributed amongst the following five muscles:

Biceps brachii (BB)	Flexor digitorum profundus (FDP)	Flexor digitorum superficialis (FDS)	Flexor carpi ulnaris (FCU)	Flexor carpi radialis (FCR)	Total Dose
300-400 units (0.6-0.8 ml)	150 units (0.3 ml)	150-250 units (0.3-0.5 ml)	150 units (0.3 ml)	150 units (0.3 ml)	1,000 units (2.0 ml)

The sites of injection should be guided by standard locations used for electromyography, although actual location of the injection site will be determined by palpation. All muscles except the biceps brachii (BB) should be injected at one site, whilst the biceps should be injected at two sites.

The dose should be lowered if there is evidence to suggest that this dose may result in excessive weakness of the target muscles, such as for patients whose target muscles are small, where the BB muscle is not to be injected or patients who are to be administered multi-level injections. Clinical improvement may be expected within two weeks after injection. Data on repeated and long term treatment are limited.

Children: The safety and effectiveness of Dysport in the treatment of arm spasticity in children have not been demonstrated.

Method of administration

The exposed central portion of the rubber stopper should be cleaned with alcohol immediately prior to piercing the septum. A sterile 23 or 25 gauge needle should be used.

Dysport is reconstituted with 1.0 ml of sodium chloride injection B.P. (0.9%) to yield a solution containing 500 units per ml of Dysport. Dysport is administered by intramuscular injection into the five muscles detailed above when treating arm spasticity.

Paediatric cerebral palsy spasticity:

Posology

The initial recommended dose is 20 units/kg body weight given as a divided dose between both calf muscles. If only one calf is affected, a dose of 10 units/kg bodyweight should be used. Consideration should be given to lowering this starting dose if there is evidence to suggest that this dose may result in excessive weakness of the target muscles, such as for patients whose target muscles are small or patients who require concomitant injections to other muscle groups. Following evaluation of response to the starting dose subsequent treatment may be titrated within the range 10 units/kg and 30 units/kg divided between both legs. The maximum dose administered must not exceed 1000 units/patient.

Administration should primarily be targeted to the gastrocnemius, although injections of the soleus and injection of the tibialis posterior should also be considered.

The use of electromyography (EMG) is not routine clinical practice but may assist in identifying the most active muscles.

Clinical improvement may be expected within two weeks after injection. Injections may be repeated approximately every 16 weeks or as required to maintain response, but not more frequently than every 12 weeks.

Method of administration

When treating paediatric cerebral palsy spasticity, Dysport is reconstituted with 1.0 ml of sodium chloride injection B.P. (0.9%) to yield a solution containing 500 units per ml of Dysport. Dysport is administered by intramuscular injection into the calf muscles when treating spasticity.

Spasmodic torticollis

Posology

Adults and elderly: The doses recommended for torticollis are applicable to adults of all ages providing the adults are of normal weight with no evidence of low neck muscle mass. A reduced dose may be appropriate if the patient is markedly underweight or in the elderly, where reduced muscle mass may exist.

The initial recommended dose for the treatment of spasmodic torticollis is 500 units per patient given as a divided dose and administered to the two or three most active neck muscles.

For rotational torticollis distribute the 500 units by administering 350 units into the splenius capitis muscle, ipsilateral to the direction of the chin/head rotation and 150 units into the sternomastoid muscle, contralateral to the rotation.

For laterocollis, distribute the 500 units by administering 350 units into the ipsilateral splenius capitis muscle and 150 units into the ipsilateral sternomastoid muscle. In cases associated with shoulder elevation the ipsilateral trapezoid or levator scapulae muscles may also require treatment, according to visible hypertrophy of the muscle or electromyographic (EMG) findings. Where injections of three muscles are required, distribute the 500 units as follows, 300 units splenius capitis, 100 units sternomastoid and 100 units to the third muscle.

For retrocollis distribute the 500 units by administering 250 units into each of the splenius capitis muscles. This may be followed by bilateral trapezius injections (up to 250 units per muscle) after 6 weeks, if there is insufficient response. Bilateral splenii injections may increase the risk of neck muscle weakness.

All other forms of torticollis are highly dependent on specialist knowledge and EMG to identify and treat the most active muscles. EMG should be used diagnostically for all complex forms of torticollis, for reassessment after unsuccessful injections in non complex cases, and for guiding injections into deep muscles or in overweight patients with poorly palpable neck muscles.

On subsequent administration, the doses may be adjusted according to the clinical response and side effects observed. Doses within the range of 250-1000 units are recommended, although the higher doses may be accompanied by an increase in side effects, particularly dysphagia. Doses above 1000 units are not recommended.

The relief of symptoms of torticollis may be expected within a week after the injection. Injections should be repeated approximately every 12 weeks or as required to prevent recurrence of symptoms.

Children: The safety and effectiveness of Dysport in the treatment of spasmodic torticollis in children have not been demonstrated.

Method of administration

When treating spasmodic torticollis Dysport is reconstituted with 1.0 ml of sodium chloride injection B.P. (0.9%) to yield a solution containing 500 units per ml of Dysport. Dysport is administered by intramuscular injection as above when treating spasmodic torticollis.

Blepharospasm and hemifacial spasm

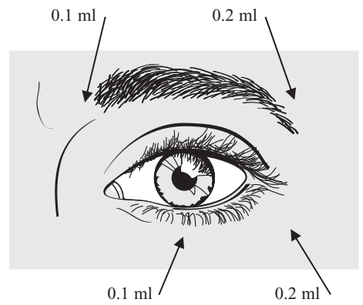
Posology

Adults and elderly: In the treatment of bilateral blepharospasm the recommended initial dose is 120 units per eye.

Injection of 0.1 ml (20 units) should be made medially and of 0.2 ml (40 units) should be made laterally into the junction between the preseptal and orbital parts of both the upper and lower orbicularis oculi muscles of each eye.

For injections into the upper lid the needle should be directed away from its centre to avoid the levator muscle. A diagram to aid placement of these injections is provided. The relief of symptoms may be expected to begin within two to four days with maximal effect within two weeks.

Injections should be repeated approximately every 12 weeks or as required to prevent recurrence of symptoms. On such subsequent administrations the dose may need to be reduced to 80 units per eye - viz -: 0.1 ml (20 units) medially and 0.1 ml (20 units) laterally above and below each eye in the manner previously described. The dose may be further reduced to 60 units per eye by omitting the medial lower lid injection.



In cases of unilateral blepharospasm the injections should be confined to the affected eye. Patients with hemifacial spasm should be treated as for unilateral blepharospasm. The doses recommended are applicable to adults of all ages including the elderly.

Children: The safety and effectiveness of Dysport in the treatment of blepharospasm and hemifacial spasm in children have not been demonstrated.

Method of administration

When treating blepharospasm and hemifacial spasm Dysport is reconstituted with 2.5 ml of sodium chloride injection B.P. (0.9%) to yield a solution containing 200 units per ml of Dysport. Dysport is administered by subcutaneous injection medially and laterally into the junction between the preseptal and orbital parts of both the upper and lower orbicularis oculi muscles of the eyes.

4.3 Contraindications

Dysport is contraindicated in individuals with known hypersensitivity to any components of Dysport.

4.4 Special warnings and precautions for use

Careful consideration should be given before the injection of patients who have experienced a previous allergic reaction to a product containing botulinum toxin type A. The risk of a further allergic reaction must be considered in relation to the benefit of treatment.

Dysport should only be used with caution under close supervision in patients with subclinical or clinical evidence of marked defective neuro-muscular transmission (e.g. myasthenia gravis). Such patients may have an increased sensitivity to agents such as Dysport which may result in excessive muscle weakness.

There are no reports of any immune response after the local administration of *Clostridium botulinum* type A toxin-haemagglutinin complex in accordance with the doses recommended when treating hemifacial spasm. Antibody formation to botulinum toxin has been noted rarely in patients (approximately 1 in 10, 000 cases) receiving Dysport.

Clinically, neutralizing antibodies have been detected by substantial deterioration in response to therapy or a need for consistently increasing doses.

Dimensions:	402 x 296 mm
Specification ref:	Leaflet-04 PS
ICN:	01460P
Proof No.:	ONE
Proof Amend Date:	25/02/09
Colours:	Black, P361U
Barcode type:	N/A
Front	
Perforation:	3 mm x 1 mm parallel to 296 measurement

Component code:	1101018701
Presentation:	Dysport 500U
Component:	Pack insert
Territory:	ASIA
Language:	English
Print supplier:	M.Y Newmarket

IPSEN

Ipsen Biopharm Ltd., Ash Road, Wrexham Industrial Estate, Wrexham, LL13 9UF, UK

Tel: +44 (0) 1978 661181
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For confirmation of Final Artwork Approval refer to electronic signature summary on PALM

For the treatment of cerebral palsy in children, Dysport should only be used in children over 2 years of age.

As with any intramuscular injection, Dysport should be used only where strictly necessary in patients with prolonged bleeding times, infection or inflammation at the proposed injection site.

This product contains a small amount of human albumin. The risk of transmission of viral infection cannot be excluded with absolute certainty following the use of human blood or blood products.

Side effects related to spread of toxin distant from the site of administration have been reported (See section 4.8), which in some cases was associated with dysphagia, pneumonia and /or significant debility resulting in death very rarely.

Patients treated with therapeutic doses may experience exaggerated muscle weakness. Patients with underlying neurological disorders including swallowing difficulties are at increased risk of these side effects. The botulinum toxin product should be used under specialist supervision in these patients and should only be used if the benefit of treatment is considered to outweigh the risk.

Patients with a history of dysphagia and aspiration should be treated with extreme caution.

Patients and their care-givers must be warned of the necessity of immediate medical treatment in case of problems with swallowing, speech or respiratory disorders.

4.5 Interaction with other medicinal products and other forms of interaction

Drugs which affect neuromuscular transmission, such as aminoglycoside antibiotics, should be used with caution.

4.6 Pregnancy and lactation

Teratological and other reproductive studies have not been performed with Dysport. The safety of its use in pregnant or lactating women has not been demonstrated.

Dysport should not be used in pregnant or lactating women, unless clearly necessary.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Very common >1/10: Common >1/100, <1/10: Uncommon >1/1000, <1/100:

Rare >1/10 000, < 1/1000: Very rare <1/10 000.

Side effects related to spread of toxin distant from the site of administration have been reported (exaggerated muscle weakness, dysphagia, aspiration/aspiration pneumonia, with fatal outcome in some very rare cases). (See section 4.4).

General

A total of approximately 7500 patients were treated with Dysport during a series of clinical trials in patients suffering blepharospasm, hemifacial spasm, torticollis or spasticity associated with cerebral palsy or stroke.

Approximately 2200 patients included in these trials experienced an adverse event.

Nervous system disorders

Rare: Neuralgic amyotrophy

Skin and subcutaneous tissue disorders

Uncommon: Itching

Rare: Skin rashes

General disorders and administration site conditions

Common: Generalised weakness, fatigue, flu-like syndrome, pain / bruising at injection site.

Arm spasticity

In 5 clinical trials involving 141 patients treated with Dysport the following adverse reactions were reported.

Gastrointestinal disorders

Common: Dysphagia

Musculoskeletal and connective tissue disorders

Common: Arm muscle weakness

Injury, poisoning and procedural complications

Common: Accidental injury / falls

Paediatric cerebral palsy spasticity

In 14 clinical trials involving approximately 900 patients treated with Dysport, the following adverse reactions were reported:

Gastrointestinal disorders

Common: Diarrhoea, vomiting

Musculoskeletal and connective tissue disorders

Common: Leg muscle weakness

Renal and urinary disorders

Common: Urinary incontinence

General disorders and administration site conditions

Common: Abnormal gait

Injury, poisoning and procedural complications

Common: Accidental injury due to falling

Accidental injury due to falling and abnormal gait may have been due to the over-weakening of the target muscle and / or the local spread of Dysport to other muscles involved in ambulation and balance.

Spasmodic torticollis

In 21 clinical trials involving approximately 4100 patients the following adverse reactions were reported:

Nervous system disorders

Common: Dysphonia

Uncommon: Headache

Eye disorders

Uncommon: Diplopia, blurred vision

Respiratory, thoracic and mediastinal disorders

Rare: Respiratory disorders

Gastrointestinal disorders

Very common: Dysphagia

Uncommon: Dry mouth

Musculoskeletal and connective tissue disorders

Common: Neck muscle weakness

Dysphagia appeared to be dose related and occurred most frequently following injection into the sternomastoid muscle. A soft diet may be required until symptoms resolve.

These side effects may be expected to resolve within two to four weeks.

Blepharospasm and hemifacial spasm

In 13 clinical trials involving approximately 1400 patients treated with Dysport, the following adverse reactions were reported:

Nervous system disorders

Common: Facial muscle weakness

Uncommon: Facial nerve paresis

Eye disorders

Very common: Ptosis

Common: Diplopia, dry eyes, tearing

Rare: Ophthalmoplegia

Skin and subcutaneous tissue disorders

Common: Eyelid oedema

Rare: Entropion

Side effects may occur due to deep or misplaced injections of Dysport temporarily paralysing other nearby muscle groups.

The profile of adverse reactions reported to the company during post-marketing use reflects the pharmacology of the product and those seen during clinical trials.

4.9 Overdose

Excessive doses may produce distant and profound neuromuscular paralysis. Respiratory support may be required where excessive doses cause paralysis of respiratory muscles. There is no specific antidote; antitoxin should not be expected to be beneficial and general supportive care is advised. Overdose could lead to an increased risk of the neurotoxin entering the bloodstream and may cause complications associated with the effects of oral botulinum poisoning (e.g deglutition and phonation).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Clostridium botulinum type A toxin-haemagglutinin complex blocks peripheral cholinergic transmission at the neuromuscular junction by a presynaptic action at a site proximal to the release of acetylcholine. The toxin acts within the nerve ending to antagonise those events that are triggered by Ca^{2+} which culminate in transmitter release. It does not affect postganglionic cholinergic transmission or postganglionic sympathetic transmission.

The action of toxin involves an initial binding step whereby the toxin attaches rapidly and avidly to the presynaptic nerve membrane. Secondly, there is an internalisation step in which toxin crosses the presynaptic membrane, without causing onset of paralysis. Finally the toxin inhibits the release of acetylcholine by disrupting the Ca^{2+} mediated acetylcholine release mechanism, thereby diminishing the endplate potential and causing paralysis.

Recovery of impulse transmission occurs gradually as new nerve terminals sprout and contact is made with the post synaptic motor endplate, a process which takes 6 - 8 weeks in the experimental animal.

5.2 Pharmacokinetic properties

Pharmacokinetic studies with botulinum toxin pose problems in animals because of the high potency, the minute doses involved, the large molecular weight of the compound and the difficulty of labelling toxin to produce sufficiently high specific activity. Studies using I^{125} labelled toxin have shown that the receptor binding is specific and saturable, and the high density of toxin receptors is a contributory factor to the high potency. Dose and time responses in monkeys showed that at low doses there was a delay of 2 - 3 days with peak effect seen 5 - 6 days after injection. The duration of action, measured by changes of ocular alignment and muscle paralysis varied between 2 weeks and 8 months. This pattern is also seen in man, and is attributed to the process of binding, internalisation and changes at the neuromuscular junction.

5.3 Preclinical safety data

There is no further pre-clinical information relevant to the prescribing physician that has not been included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Albumin and Lactose.

6.2 Incompatibilities

None known.

6.3 Shelf life

Do not use after the expiry date shown on the box.

The product may be stored for up to 8 hours at 2-8°C following reconstitution.

Since the product does not contain an anti-microbial agent, from a microbiological point of view, it is recommended that the product should be used immediately following reconstitution.

6.4 Special precautions for storage

Unopened vials must be maintained at temperatures between 2°C and 8°C. Dysport must be stored in a refrigerator at the hospital where the injections are to be carried out and should not be given to the patient to store.

Reconstituted Dysport may be stored in a refrigerator (2-8°C) for up to 8 hours prior to use. Dysport should not be frozen.

6.5 Nature and contents of container

bromobutyl

Nature of container/closure:

Type 1 glass vials 3 ml capacity. 13 mm chlorbutyl freeze-drying closures oversealed by 13 mm aluminium overseals with centre hole, crimped over.

Contents of container:

A white lyophilised powder for reconstitution.

6.6 Special precautions for disposal

Immediately after treatment of the patient, any residual Dysport which may be present in either vial or syringe should be inactivated with dilute hypochlorite solution (1% available chlorine). Thereafter, all items should be disposed of in accordance with standard hospital practice.

Spillage of Dysport should be wiped up with an absorbent cloth soaked in dilute hypochlorite solution.

7 UK MARKETING AUTHORISATION HOLDER (Country of Origin)

Ipsen Limited
190 Bath Road, Slough
Berkshire, SL1 3XE

8 UK MARKETING AUTHORISATION NUMBER (Country of Origin)

PL 6958/0005

9 MANUFACTURER

Ipsen Biopharm Limited
Ash Road, Wrexham Industrial Estate
Wrexham, LL13 9UF, UK

10 DATE OF REVISION OF THE TEXT (UK)

June 2007

IPSEN

DETACH HERE AND GIVE INFORMATION TO PATIENT

Dysport®

Clostridium botulinum type A
toxin-haemagglutinin complex

Less commonly Dysport may cause itching.

Rarely skin rashes and muscle weakness may be experienced.

Side effects related to the spread of toxin distant from the site of administration have been reported (exaggerated muscle weakness, difficulty with swallowing or inhalation of foreign material which in very rare cases may have been fatal).

Injections into the arm muscles for the treatment of arm spasticity

The most common side effects include:

- Arm muscle weakness
- Accidental injury / falls
- Difficulty in swallowing

Injections into the calf muscles in children with cerebral palsy

The most common side effects are:

- The muscles of the lower leg may be temporarily over weakened, leading to changes in walking pattern or possibly increased tendency to falls.
- Weakness of the leg muscles
- Urinary incontinence
- Diarrhoea
- Vomiting

Injections into the neck muscles for the treatment of spasmodic torticollis

The most common side effects include:

- Difficulty in swallowing certain foods
- The neck may feel weaker
- A change to the tone of the voice

Less common side effects are:

- The mouth may feel dry
- Some difficulty in seeing clearly
- Headache

Rarely Dysport may cause breathing difficulties.

These side effects may be expected to resolve within 2 to 4 weeks.

The doctor should be informed immediately if any breathing difficulties or if any difficulties in swallowing are experienced.

Injections around the eye for the treatment of blepharospasm or hemifacial spasm

The most common side effects include:

- Slight eyelid droop
- Dry eyes
- Some difficulty seeing clearly
- More tears than usual
- Swelling of the eyelid
- Facial muscle weakness

Less commonly the facial nerves may become paralysed.

Rarely the edge of the eyelid may turn in towards the eyeball and the eye muscles may become paralysed.

The doctor should be informed immediately if very dry eyes are noticed.

If any side effect becomes troublesome or causes concern, the doctor should be informed.

Most side effects are mild and transient.

Further information

Dysport will be stored in a refrigerator (2°C-8°C) at the hospital where the injections are carried out. This medicine should not be given to the patient to store.

Do not use after the expiry date shown on the box.

Date of last revision of this leaflet (UK)

June 2007

Product licence number (UK)

PL 6958/0005

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Dimensions:	402 x 296 mm
Specification ref:	Leaflet-04 PS
ICN:	01460P
Proof No.:	ONE
Proof Amend Date:	25/02/09
Colours:	Black, P361U
Barcode type:	N/A
Front	

Perforation:

3 mm x 1 mm parallel to 296 measurement

Component code:	1101018701
Presentation:	Dysport 500U
Component:	Pack insert
Territory:	ASIA
Language:	English
Print supplier:	M.Y Newmarket

IPSEN

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For confirmation of Final Artwork Approval refer to electronic signature summary on PALM