

# **BOTOX FACT SHEET**

## **WHAT IS BOTOX?**

BOTOX (BOTULINUM TOXIN TYPE A) IS AN INJECTABLE BIOLOGICAL PRODUCT THAT CAUSES TEMPORARY MUSCLE PARALYSIS BY INTERFERING WITH THE RELEASE OF ACETYLCHOLINE (AN NEUROTRANSMITTER TO THE MUSCLE) FROM THE NERVE. BOTULINUM TOXIN IS PRODUCED BY THE BACTERIA CLOSTRIDIUM BOTULINUM. DESIGNATED AN ORPHAN DRUG BY THE FDA, BOTOX HAS NOW BEEN IN BROAD USE FOR VARIOUS MUSCLE DISORDERS FOR OVER 10 YEARS. BOTOX IS MANUFACTURED BY ALLERGAN, INC AND DISTRIBUTED TO PHYSICIANS IN A FREEZE-DRIED FORM .

## **WHAT IS THE MECHANISM OF ACTION?**

WHEN INJECTED IN SMALL AMOUNTS, BOTOX CAUSES TEMPORARY PARALYSIS OF THE INJECTED MUSCLE BY INTERFERING WITH THE RELEASE OF ACETYLCHOLINE FROM NERVE CELLS. THIS MUSCULAR PARALYSIS CAUSED BY THE DRUG RELIEVES PATIENTS OF SPASM AND SPASTICITY. THE EFFECTS OF BOTOX LAST ON AVERAGE 3-4 MONTHS.

## **HOW WAS BOTOX DEVELOPED?**

FOR THE PAST 20 YEARS, SCIENTISTS HAVE BEEN EXAMINING THE THERAPEUTIC POTENTIAL OF BOTULINUM TOXIN TYPE A. DR. ALAN SCOTT, OF THE SMITH KETTLEWELL EYE RESEARCH INSTITUTE, IS CREDITED WITH PIONEERING ITS USE IN EYE CONDITIONS.

## **HOW LONG HAS BOTOX BEEN IN CLINICAL INVESTIGATION?**

BOTOX HAS BEEN UNDER CLINICAL INVESTIGATION FOR APPROXIMATELY 20 YRS. IN 1973, DR. ALAN SCOTT SUBMITTED AN APPLICATION TO THE FOOD AND DRUG ADMINISTRATION AND CLINICAL STUDIES WERE CONDUCTED OVER THE NEXT NINE YEARS. IN 1982, A MULTICENTER CLINICAL STUDY WAS ORGANIZED INVOLVING 200 PHYSICIANS AND 10,000 PATIENTS. BASED ON THESE RESULTS, THE FDA APPROVED BOTOX FOR CLINICAL USE IN 1989.

## **WHAT SIDE EFFECTS ARE PRODUCED BY THE BOTOX INJECTION? WHAT ARE THE LONG TERM COMPLICATIONS OF BOTOX?**

THERE IS NO EVIDENCE OF LONG TERM COMPLICATIONS FROM BOTOX THERAPY. SIDE EFFECTS ARE CONSIDERED MINOR AND TRANSITORY. OVER WEAKNESS OF MUSCLES MAY OCCUR BUT IS SELF CORRECTING AS THE EFFECT OF THE TOXIN DIMINISHES. THERE HAVE BEEN RARE REPORTS OF LOCAL RASHES AND FLU LIKE SYMPTOMS.

**WHY DOES THE PACKAGE INSERT FOR BOTOX INDICATE ITS USE ON CHILDREN OF 12 YEARS OF AGE AND OLDER?**

AT THE TIME BOTOX WAS SUBMITTED TO THE FDA IN 1985, THERE WAS NO COMPLETED DATA AVAILABLE ON CHILDREN UNDER 12 YEARS OF AGE. BOTH THE CLINICAL DATA AND PRACTICAL MEDICAL USE OF BOTOX IN THE PEDIATRIC POPULATION HAS OCCURED SINCE 1989.

**IS THERE ANY POSSIBILITY OF PERMANENT DAMAGE AS A RESULT OF BOTOX TREATMENT?**

SINCE RECOMMENDED TREATMENT DOSAGES ARE SMALL, THE RISK OF OVERDOSE IS SMALL. THE ENTIRE CONTENTS OF ONE VIAL OF BOTOX IS 20 TO 30 TIMES BELOW THE TOXICITY LEVEL IN HUMANS.

**DOES BOTOX INTERACT WITH ANY OTHER MEDICATIONS?**

IN MOST CASES, PATIENTS CAN BE TREATED WITH BOTOX SAFELY REGARDLESS OF OTHER DRUG THERAPY. HOWEVER, THE EFFECTS OF BOTOX CAN BE POTENTIATED BY AMINOGLYCOSIDE ANTIBIOTICS AND OTHER DRUGS THAT INTERFERE WITH NEUROMUSCULAR TRANSMISSION.

**ARE THERE CLINICAL INDICATORS THAT MIGHT SUGGEST A PATIENT WILL NOT RESPOND TO BOTOX OR CAN THIS BE DISCOVERED ONLY AFTER ADMINISTRATION?**

THERE IS NO ACCURATE INDICATORS OF POTENTIAL RESISTANCE TO BOTOX. MOST PATIENTS REALIZE SIGNIFICANT BENEFITT FROM THE BOTOX INJECTION,

**HOW QUICKLY ARE THE RESULTS OF THE BOTOX INJECTION REALIZED?**

THE FIRST NOTICEABLE RESULTS CAN BE SEEN WITH TWO TO THREE DAYS. HOWEVER THE MAXIMUM EFFECTIVENESS IS NOT REALIZED UNTIL SEVEN TO TEN DAYS?