

Written Informed Consent Form**For Adult Subjects \geq 18 Years of Age****Study Identification:** [TOC100224](#)

Study Title: A Randomised, Observer-blind, Multicentre, Non-inferiority, Comparative, Phase III Study of the Safety and Efficacy of Topical 1% SB-275833 Ointment, Applied Twice Daily for 5 Days, versus Topical 2% Sodium Fusidate Ointment Applied Three Times Daily for 7 Days in the Treatment of Adult and Paediatric Subjects with Impetigo.

Version Number: 01 **Date:** 02/12/04**Company Name:** GlaxoSmithKline**Subject Identification:** [Insert subject ID here](#)**Purpose/Description/Procedures/Duration****What is this leaflet about?**

You been asked to take part in a clinical research study testing a new medicine. This medical research study is testing a new medicine for use in people who have an infected skin disease known as impetigo that is caused by common germs (bacteria). The new medicine, named 1% SB-275833 ointment, will be studied to see how well it works and how safe it is when applied to the skin two times a day for five days. People treated with 1% SB-275833 ointment will be compared to people treated with another ointment containing 2% sodium fusidate a well known medicine.

Before you decide whether to participate it is important for you to know why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it if you wish with your friends, relatives and your personal doctor (i.e., your general practitioner or primary care physician). Ask your doctor if there is anything that is not clear or if you would like more information. Take the time to decide whether or not you wish to take part.

Who is paying for this study?

The study doctor and/or the institution is/are paid to conduct this research study by GlaxoSmithKline.

What is the purpose of the study?

Researchers want to find out if a drug called 1% SB-275833 ointment can help people with the skin infection known as impetigo that is infected with common germs (bacteria). SB-275833 ointment, which belongs to a new class of antibiotic called pleuromutilins, is an investigational medicine. An “investigational medicine” is a drug that is still being tested and is not approved for use and sale.

Some people in the study will use 1% SB-275833 ointment and other people will use an antibiotic called 2% sodium fusidate ointment which is a well known licensed medicine widely used as a topical treatment for impetigo. The study doctor will see how well 1% SB-275833 ointment works and how safe it is by comparing it to 2% sodium fusidate ointment.

What treatment will I receive?

Which treatment you receive is determined by chance, like flipping a coin. The randomisation into treatment groups is determined by a computer that has no information about the individual participants. In this study you will have a two in three chance of receiving the 1% SB-275833 antibiotic ointment and a one in three chance of receiving 2% sodium fusidate antibiotic ointment.

You will know what type of treatment you are receiving. The person providing you with the study medicine will also know what treatment you are receiving. But your doctor treating you will not know which study treatment you are receiving. During the study, you will be asked not to discuss the type of ointment you are using at anytime with your doctor treating your infection as it is important that he or she does not know which treatment you are using. This type of research study is referred to as an “Observer Blind” Study.

If you agree to take part in this study you will receive one of following treatments.

1% SB-275833 ointment applied twice daily for 5 days

OR

2% sodium fusidate ointment applied three times daily for 7 days

How long will I be in the study?

If you agree to take part in this study and if you meet all of the conditions required for entry, you will be asked to participate in the study for approximately 14 days. During this time, you will need to visit the clinic a total of four times, including this visit, during the following days: Day 1, Day 7, Day 9 and Day 14. You must try to come to the clinic for all the visits, so that the doctor can make sure that your impetigo is getting better and is finally cured.

What procedures are to be carried out on me during the study?

During the clinic visits, the following tests and procedures will be performed on you:

- A general physical examination, which includes height, weight, temperature, heart rate and blood pressure.
- Examine your skin and questions will be asked about your skin infection.
- About a tablespoon of your blood will be taken with a needle, and a urine sample will be collected, a total of two times during the study. This is to make sure that your blood cells and the chemicals in your blood are normal, and not affected by either of the study treatments.
- If you are female, and can have children you will be asked to give a urine sample at the time of the first and last visits, to determine if you are pregnant. The nurse or doctor will explain to you how to collect the urine sample. If the urine test shows that you are pregnant, you will not be allowed to enter the study. This is because we are not sure that the study drug will not hurt the unborn baby.
- A sample from your infected skin will be taken to see what germs (bacteria) are causing the infection. The sample will be taken by swabbing the site of infection with a sterile cotton swab. This sample will be taken at the beginning of the study, and possibly at other study visits, if you are getting better, but still have signs of infection. If you do not want to have samples collected as described above, you should not agree to enter in this study.
- A swab sample from the inside of your nose will also be taken at selected times during the study, to see if there are germs (bacteria) in your nose that may be related to the germs that is causing your impetigo.
- A swab sample may also be taken from your infected skin and nose if you are not getting better and the doctor decides to give you a different medicine
- You will be given a diary card and told how to fill it out to record each time you apply study medication to your skin. You will need to bring the diary card with you to the clinic visits. Your doctor will take the diary card to add to your file on the visit after you complete the course of study medication

Your doctor will ask you not to apply any other medications to your area of infected impetigo lesion(s), other than the study medication, for the length of the study. This is necessary so the effects of 1% SB-275833 ointment can be fully measured without any interference from other medications. If you have any other skin conditions you may continue to use your normal medications as directed by your study doctor. While participating in this study, no prescription antibiotics may be taken

This medical research study is being conducted according to the International Conference of Harmonization (ICH) (international) regulations. It has also been approved by an Ethic Committee /Institutional Review Board, which is a committee set up to protect your rights as a patient and as a research subject.

How many people are participating in the study?

The approximate number of subjects involved in the study.

Consider the subject recruitment plan for the study and provide information in the ICF accordingly. Explain that recruitment of new participants will cease on a study when the targeted enrollment has been achieved.

There will be approximately 520 people with impetigo from European and International countries asked to participate in the study; people will be both adults and children aged from 9 months of age. Your study doctor will inform you if this total is reached for the study and whether your participation in the study will be needed.

What are the Risks/Inconveniences?

All drugs can cause side effects in some people. In healthy people, who agreed to have their skin abraded (i.e., lightly scraped) on purpose, and who received SB-275833 ointment at a concentration two times higher than will be used in this study, the most common side effect was skin irritation. In another study in people with simple skin infections, the most common side effect in people treated with 1% SB-275833 ointment was mild itching.

The most common side-effects of sodium fusidate ointment are minor and those known at this time are: mild irritation at area of application, allergic reaction at the site of application: including redness, swelling, rash, burning sensation and itching.

The drugs used in this study may involve other risks that are not known at this time. You should get medical help and contact the study doctor or study staff if you should have any of these or any other side effects during the study.

You may have some discomfort at the infection site when the bacterial sample of the infected lesion area is collected. The sample taken from the inside of the nose is taken at the very front of the nasal opening (nares) and you may feel some fullness or very light pressure (much like a finger in the nose).

When the blood is drawn, you may experience some discomfort when the needle goes through the skin. You may feel faint, experience mild pain, bruising, irritation or redness at the site where the needle went into the skin. In rare cases, an infection may develop.

If you work, your work schedule may be interrupted by visits to the clinic. If the four visits will be a hardship for you, then you should not agree to enter this study.

If you are female, you cannot be in this study if you are pregnant or nursing a baby. If you decide to be in the study:

- You must not be pregnant.
- You must not plan to become pregnant during the study.
- You must not be nursing a baby.

If a female is pregnant or nursing a child while using 1% SB-275833 ointment or 2% sodium fusidate ointment there may be risks to the unborn baby or nursing child.

Nobody knows what these risks are right now. Some drugs cause babies to be born prematurely (earlier than they should be) or to have birth defects.

If you are female you will be required to have two pregnancy tests during the study, one on the first day and the other on the last day of the study. A pregnancy test does not stop you from becoming pregnant.

If you are a female who can have children, the study doctor will talk to you about birth control options you must use during the study. Some types of birth control will not work when you are taking certain drugs. The birth control options you can use during the study are:

- hormonal contraceptives (such as birth control pills or implants) + barrier contraception (such as a condom or diaphragm)
- IUD (intra-uterine device)
- diaphragm or condom + contraceptive cream, jelly, or foam

If you think that you are pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you will not be able to continue in the study. The study doctor may request to have information about your pregnancy and the birth of the child. The study doctor may share this information with the sponsor and ethics committee.

What are the Benefits?

All people in the study will receive an active medication. In laboratory tests it has been shown that 1% SB-275833 ointment works very well against different types of germs (bacteria), including some germs (bacteria) that are resistant to other antibiotics used to treat skin infections. 2% sodium fusidate ointment is a widely used antibiotic for the treatment of various skin infections including impetigo caused by common germs (bacteria).

Your participation in this study may add to the medical knowledge about the use of this new medicine. If you agree to participate in this study, SB-275833 may or may not be beneficial in treating your skin infection or improving symptoms. The information learned from this study may help to establish a new medicine for the treatment of impetigo caused by common germs (bacteria).

You will get medical attention often and will have tests done to watch your health at no extra cost to you.

Are there Alternative Treatments?

Before you decide whether or not to take part in this study, you may wish to consider other treatment options to treat your impetigo, that include other topical antibiotic

ointment or creams or oral antibiotics. Your doctor will describe these to you based on your medical history and the treatment you have received to date.

Compensation for Study-Related Injury

In the event that you suffer any injury attributable to the administration of a medicinal product within the trial or any clinical intervention or procedure required under the trial that would not have occurred but for your inclusion in the trial, you will be compensated. A copy of the guidelines covering compensation for any such injury can be obtained from your study doctor.

Will I be paid for taking part in the study?

You will receive no payment for taking part in this study

Will there be any expenses/costs as result of me taking part in the study?

GSK, has made provisions with your study doctor to reimburse you for the cost of travelling to and from study visits and for other miscellaneous costs (such as expense for a meal), up to a maximum of [].

Who are the contact(s) for Answers to Pertinent Questions about Research and Subject's Rights and Contact(s) in the Event of an Injury?

You have the right to ask _____ at _____ any questions concerning this study at any time.

If you have any questions concerning your rights as a subject in a research study, you should contact _____ at _____ at any time.

If you believe have sustained a research-related injury, you should contact _____ at _____ at any time.

Can my participation in the study be terminated?

Your participation in the study may be stopped for any of the following reasons:

- i. If you don't follow the study doctor's instructions.
- ii. The study doctor decides it is in the best interest of your health and welfare to stop.
- iii. There aren't enough people in the study, or the study has reached the required number of people.
- iv. GlaxoSmithKline stops the study at this study site for other reasons not known now.

Is participation voluntary and can I end my participation in the study?

Your participation in this study is voluntary. If you do decide to take part, you will be given this information to keep and be asked to sign this consent form. You may refuse to take part in this study, or once in the study you may decide to stop your participation at any time. You must inform the study doctor if you decide to do this. Your decision not to take part in the study or to stop participating in the study will not affect your current or future medical care, or any benefits to which you may otherwise be entitled.

Contact your study doctor or clinic should you decide not to continue your participation in the study. He/she will explain the best way for you to stop your participation in the research study.

Should you choose to end your participation in the study, information and study data collected before withdrawal from the study will be used by GSK.

What about Confidentiality and Data Privacy?

Maintaining confidentiality is important to GlaxoSmithKline. Your personal information (for example, your gender, age, the details of your medical conditions) and other information (the data collected by GlaxoSmithKline as part of the study) will be identified by a number (i.e., coded). Your name will not appear in any publications or reports produced from this study.

GlaxoSmithKline will keep the information and the results collected about you in this study. Your name and address are not included in the information kept by GlaxoSmithKline - only your study doctor will keep this information. GlaxoSmithKline has told your study doctor to keep the information about you in a secure place. GlaxoSmithKline will comply with internal procedures to protect personal and other information even in countries where data privacy laws are less strict than in Europe or in the US.

By agreeing to take part in this research study you will be allowing certain persons to see the information about you (both personal, including your name, and other information) held by the study doctor. Your information will be looked at to confirm that it is correct and that it is related to you. Only certain people working for GlaxoSmithKline and organizations acting on behalf of GlaxoSmithKline, and the government regulatory authorities will do this. These persons are required to maintain the confidentiality of your information.

Your information will be processed electronically (i.e., by a computer) or manually and analysed to determine outcome of this study. GlaxoSmithKline may use your information for other medical/health care purposes related to development of this drug. For this purpose your coded information will be used.

Your information may/could be sent to regulatory authorities, to the independent ethics committee, to other doctors and/or organisations working with GlaxoSmithKline. It may also be sent to other GlaxoSmithKline sites in this country and in other countries where

there may be different or lesser standards for looking after it. GlaxoSmithKline will apply the same standard in the protection of your information to the extent permitted by law.

You have the right to ask the study doctor about the data being collected on you for the study and about the purpose of this data. You have the right to ask the study doctor to allow you to see your personal information and to have any needed corrections to it made.

You have the right to withdraw consent to participate further in the study, the result of which is that no new information will be collected from you and added to your existing data or to a database.

What will happen to my blood samples and tissue samples from nose and skin that are collected for the study?

As part of the study, blood samples, skin tissue and nose samples will be taken to check your condition. The samples stored will not be labelled with information that directly identifies you, but will be labelled with a number that can be linked to you. The link between the sample's number and information identifying you will be kept at the study site.

Your blood and tissue samples may be sent to GlaxoSmithKline or to other researchers working with GlaxoSmithKline.

What happens if new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. If this happens, we will tell you about new information that may affect your willingness to stay in this study.

I confirm that I have read the statements in the informed consent form 01, dated _____ (dd/mm/yyyy) for this study. I confirm that the study information and procedures have been explained to me by _____ on _____ during the consent process for this study.

I confirm that I have had the opportunity to ask questions about this study and I am satisfied with the answers and explanations that have been provided.

I have been given time and opportunity to read the information carefully, to discuss it with others and to decide whether or not to take part in this study.

I voluntarily consent to take part in this study.

Subject's Signature _____

Date: _____

DD/ MM/ YY

**Printed name of
Subject** _____

**Signature of Person
conducting Consent** _____

Date:

DD/ MM/ YY

**Printed Name of
Person conducting
Consent** _____