

Vicks First Defence PMCF Survey

Survey-Specific Patient Information Leaflet (SSPIL)

INTRODUCTION

As part of a planned process to constantly monitor performance of Vicks First Defence, the manufacturer (Procter & Gamble) is conducting a product survey. This survey is observational – it will not alter your use of the product in any way. The survey is intended to examine how the device performs in normal use.

The survey is one part of a wider Post-Market Clinical Follow-Up (PMCF) system that routinely monitors the performance of the product. PMCF is something that is normally required for all medical devices. To date, there have been no serious safety concerns in relation to Vicks First Defence.

All information collected will be reviewed regularly. If the data indicates any problems or concerns, then appropriate action will be taken without delay.

Information collected will be treated confidentially and according to all relevant data protection laws. Under normal circumstances it will not be possible to identify you on the basis of data entered into the survey.

REQUEST FOR YOUR PARTICIPATION

Procter & Gamble would like your consent to collect information about your use of Vicks First Defence for inclusion in the survey. Collecting information from individuals such as yourself will help Procter & Gamble to learn as much as possible about how the product is performing.

Participation in the survey is entirely voluntary and you have the right to not to give consent.

The decision on whether to consent to data entry is yours and yours alone. Even if you do consent to your data being used in the survey, you may later withdraw your consent whenever you like and for any reason. Doing so would cause Procter & Gamble to immediately cease collecting information about

you. Note, however, that the withdrawal of your consent will not affect Procter & Gamble's right to keep and use data previously provided by you.

RISKS FROM PARTICIPATION

There are no risks or benefits to you directly resulting from participating in the survey. Participation is free of charge for you; you will not be paid for participating in the survey.

THE DATA THAT IS PROCESSED

Should you choose to participate, the following information will be collected in relation to you:

- Gender
- Age range
- Cold symptoms severity and duration
- Change in symptoms over several days
- Exposure to anyone showing symptoms of a cold
- Details relating to your use of the product – how often, for what reason
- Any side-effects, symptoms or problems related to product use
- Whether you would recommend the product
- Your perception of how the product performed

In rare circumstances – for example, if you described a problem or side effect that was potentially significant – the Smart-Trial system may need to contact you to provide further information to Procter & Gamble's product safety team. This information will be passed to Procter & Gamble's product safety team as "pseudonymised data" (see below). This exception is to help ensure your safety and the safety of others.

You would enter data using a secure online system through your computer, smartphone or tablet. The computer system that will be used to collect and store data is called "Smart-Trial"; it is designed specifically for the collection of this kind of data and meets all relevant data protection requirements.

MAINTENANCE OF CONFIDENTIALITY

Your data will be treated in the strictest confidence.

The survey will be “pseudonymised”. This means that personal identifiers will not be visible to Procter & Gamble and will only be seen by the Smart-Trial system when you enrol; they will then be stored securely.

Your pseudonymised data will be combined with a ‘pool’ of data from other individuals for analysis. Both your individual pseudonymised data and the pooled data may be seen by employees of Procter & Gamble, nominated agents and contractors, and medical device regulators both in Europe and elsewhere. Individuals looking at pseudonymised data will not be able to identify you from the data they see.

Procter & Gamble’s nominated contractors may include a company called Mantra Systems Ltd, a consultancy firm that is advising on the design and conduct of the survey. Mantra Systems will be bound by this data protection framework and will only have access to pseudonymised or pooled data.

Pooled data derived from this survey may be presented at academic conferences, be published in medical journals, and be used in marketing material by Procter & Gamble.

Some of the data resulting from the survey may be linked to other sources of data (such as any product complaints) to form a more complete picture about the device’s safety and performance.

Subject Number

In this survey, you will be identified only by a Subject Number that is automatically allocated by the system on your enrolment. This will not be based on your name, date of birth, hospital or NHS number, or any other personal identifier.

RETENTION PERIOD

Information will be held securely for at least 10 years following enrolment.

LEGAL BASIS FOR THE PROCESSING OF YOUR DATA

Your personal data is processed on the basis of your consent and that it is necessary for compliance with regulatory requirements for ongoing analysis of

medical device safety and performance. In the UK, approval of an ethics committee will not be required for performance of this survey since it does not alter use of the product. If you are resident in a country outside the UK, or if UK requirements for ethics approval change, then ethics approval will be sought and obtained before commencing data collection.

Procter & Gamble are only allowed to process your individual or pooled pseudonymised data if you consent and if all necessary approvals have been obtained from relevant bodies.

RECIPIENTS OF PERSONAL DATA

We may disclose your pseudonymised data to our data processors, for example companies providing necessary IT services. In such cases, data processing agreements are entered into to ensure that your personal data is processed appropriately.

Your pseudonymised personal data may be transferred to data processors outside the UK and EU. In such cases, adequate safety measures will be implemented to ensure that your personal data is protected. More information may be obtained from Procter & Gamble's Privacy Policy.

YOUR RIGHTS

You have the right to receive information on whether or not personal data concerning you has been processed and, in such cases, get access to such personal data and also information regarding the personal data and how it has been processed.

You have the right to have inaccurate personal data concerning you rectified without undue delay. Taking into account the purposes of the processing, you also have the right to have incomplete data about you completed.

You have, under certain circumstances, the right to have personal data concerning you erased, for example if the personal data are no longer necessary in relation to the purposes for which they were collected or if the data have been unlawfully processed.

In some circumstances you have the right to obtain restriction of the processing of your personal data. For example, if you contest the accuracy of the personal data, you can also require that the processing of your personal

data is restricted for such a period that enables the accuracy of the personal data to be verified.

You have the right to withdraw consent provided by you at any time. This can be done by contacting Procter & Gamble. If your consent is withdrawn, no further data relating to you will be collected. However, personal data attributable to you may be processed even though consent is withdrawn if the processing is necessary for scientific purposes.

You have the right to receive the personal data relating to you and that you have provided, in a commonly used electronic format. You have the right to transmit that data to another controller (data portability).

You have the right to complain about the processing of your personal data by contacting Procter & Gamble, and/or the UK Information Commissioner's Office (ICO).

QUESTIONS AND CLARIFICATION

If you have any questions about this survey, then Procter & Gamble will be happy to answer them. You should be sure that your questions have been answered to your satisfaction before giving your consent.

CONTACT DETAILS

In the event that you require information about the survey, further information can be obtained by contacting Procter & Gamble at:

ConsumerRelation.im@pg.com

Please retain a copy of this Leaflet for your records.