

## INDIVIDUAL INFORMATION NOTE

### POST-MARKETING CLINICAL FOLLOW-UP STUDY OF MULTIPURPOSE ISOTONIC

Dear Sir or Madam,

If you are a user of the MULTIPURPOSE ISOTONIC, either for yourself or for your child, or if your child has used it on his or her own and you are asking him questions<sup>[HT1]</sup>, UNITHER INDUSTRIES (UI)<sup>1</sup> would like to invite you to take part in a post-marketing clinical follow-up study of this product. This is a survey designed to collect information directly from users of the MULTIPURPOSE ISOTONIC solution. You, and your child (if applicable), are free to participate or not. Please read the information below carefully before making your decision.

UI would like to know what users of the MULTIPURPOSE ISOTONIC solution think about its use (for example for the eyes, for the ears or for anything else), its perceived effectiveness and whether it is well tolerated or whether users encounter any difficulties when using it. This information is important because it will help us to know whether MULTIPURPOSE ISOTONIC is meeting users' expectations and/or to identify areas for improvement.

If you agree to take part, after giving your consent for your personal data to be processed, you will be able to complete an online survey which only takes a few minutes.

This survey is governed by Act no. 78-17 of 6 January 1978, as amended, on data processing, data files and individual liberties, and by the General Data Protection Regulation, known as the GDPR or Regulation (EU) 2016/679. Personal data may only be processed if you have given your prior consent, in accordance with Articles 6 point 1.a) and 9 point 2.a) of the GDPR.

Your identity and contact details will be known only to CEN<sup>2</sup>, the company responsible for putting the questionnaire online and for paying the compensation in return for your participation. For the purposes of the survey, you will be identified by a unique number without any mention of your first or last name in the online questionnaire.

The coded data (made confidential), for example your answers to the questions associated with the unique number, will be communicated to UI and, if necessary, to independent experts responsible for re-analysing the data to verify the results of the survey under strict security conditions.

The data you provide in the questionnaire will be processed for statistical analysis by CEN. Computer processing does not involve automated decision-making. This means that personal data will not be processed automatically by algorithms, i.e. without the intervention of a human being, for profiling purposes for example.

You have the right to access the data you have provided and to request that it can be corrected or completed. You may also request that the processing of this data to be restricted.

Even if you agree to take part in the survey, you may at any time withdraw your consent to the processing of the data you have provided as part of the survey. In this case, the data previously collected must be deleted. You also have the right to portability of the data collected as part of this survey.

This survey provides for data to be kept for 2 years after the end of the analysis of the survey data. Thereafter, the data will be archived in accordance with current regulations.

You may exercise your rights at any time and without having to justify yourself. As UI does not have access to your identity, we recommend that you first contact CEN (dpo@groupecen.com). However, if you wish, you may exercise your rights with UI's Data Protection Officer (dpo@unither-pharma.com). In this case, your identity (surname and first name) will be made available to him/her.

In the event that you are unable to exercise your rights, you also have the right to lodge a complaint concerning the processing of personal data with the personal data control authority of the country in which you habitually reside.

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<sup>1</sup> UNITHER INDUSTRIES, Zone industrielle Le Marcoulet, 17 avenue des Portes Occitanes, 03800 Gannat (data controller)

<sup>2</sup> CEN, 18 rue Pauline Kergomard, 21000 Dijon (UI subcontractor)

## INFORMATION NOTE FOR A CHILD

Hello,

To treat you, your mum or dad has used MULTIPURPOSE ISOTONIC solution on you, or you have used the MULTIPURPOSE ISOTONIC solution on your own.

The company that manufactures this product has asked your mum or dad to take part in a survey to find out whether the product is satisfactory. As you're a child, you can't take part on your own, and if you want to answer the questions, you'll have to do it with your mum or dad.

You are free to say yes or no to taking part in this survey. Take time to read or listen to the whole text and ask your mum or dad any questions you may have before making your decision.

### **Why this survey?**

The company that makes this product wants to know the opinions of many people who, like you, have used or are using it. This information is very useful because it can help the company find out if everyone is happy with the product, if it works well, if it's easy to use, or if people have encountered difficulties that could be corrected.

### **How will the survey work?**

If you agree to take part, your mum or dad will answer a few questions about using the product on a website. At no point in the survey will you be asked for your first or last name. The people who work for the company and who will analyse all the answers must not know who has answered the questions. This is very important because, unless it is absolutely necessary, no one needs to know that you are taking part in this survey.

### **What are your rights?**

There are laws to protect you and to make sure that the answers to the survey questions are used correctly and for the right reasons.

If you refuse to take part, there will be no consequences and of course you can continue to benefit from the product if you need it.

If you agree to take part, you must tell your mum or dad, who will have to confirm this in order to answer the survey questions. You are free to change your mind and you can tell your parents, who will know what to do to respect your choice. You also have the right to ask the company for more information about how your answers to the survey will be used. Your mum or dad will have been given all the necessary details about the protection and use of your answers and will be able to help you.

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