

I-NHALE SUPPORT PROGRAMME WELCOME PACK

Welcome to the I-nhale Support Programme managed by Bionical Solutions Ltd. (Bionical) on behalf of Zambon UK Limited.



I-nhale
Support Programme



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INTRODUCTION

What's contained in this welcome pack

This booklet is designed to provide you with information about the I-nhale Support Programme, explain about the Service and how we will work to support you and your NHS Clinical Team.

This booklet includes the following:

- Introduction to the I-nhale Support Programme
- Service Overview
- Role of the Patient Care Advisors
- I-neb and Replacement Parts - ordering and delivery information
- Role of the Clinical Trainers
- About Bionical
- Quality of the Service
- Frequently Asked Questions
- How to Contact the I-nhale Support Programme



WHAT'S DOES THE SERVICE LOOK LIKE AND WHO IS IT FOR?

The Service is designed to support patients and carers using Promixin and the I-neb. A dedicated patient support telephone service is available Monday to Friday 9.00am to 5.00pm (excluding Bank Holidays).

This Service is managed by a team of Patient Care Advisors who are trained in providing the I-nhale Support Programme to you. The phone number is to the right.

The Service is for people who have been prescribed Promixin. If you have not taken Promixin for more than 3 months, you will be unable to access the Service, but this will be resumed as soon as you start to use Promixin again.

If you are unsure whether you can receive this Service, please contact your doctor or call the team on the number to the left.

WHO IS PROVIDING THE I-NHALE SUPPORT PROGRAMME?

The I-nhale Support Programme has been developed and funded by Zambon UK Limited, who also provide Promixin in the UK for patients. This Service is provided for any patient prescribed Promixin and using the I-neb.

Bionical manage the I-nhale Support Programme and operate the Service with a team of Patient Care Advisors and Clinical Trainers who are employed by Bionical on behalf of Zambon UK Limited.

The Patient Care Advisors will answer the phone and will be your first point of contact with the Service. The Clinical Trainers will train you to use your I-neb device and support you with any more complex questions or problems you may have with it.

ABOUT BIONICAL

Bionical provides healthcare support to patients in partnership with the NHS and pharmaceutical companies. Providing excellent patient care is at the forefront of everything we do.

At Bionical, each of us embraces our responsibility to act as an ambassador for our company, bringing our core values to life in all that we do. We truly believe that every experience matters, and we will do all we can to support you when you are on the I-nhale Support Programme.

The staff who deliver the Service to you are all employed by Bionical and they have received specific training so that they are able to provide you with the support you need.



PATIENT CARE ADVISORS

The Patient Care Advisors will always do their best to support you. You can call them with any query you have in relation to using the I-neb with Promixin.

If your issue cannot be addressed by them they will ask one of the Clinical Trainers to contact you. You can be confident that the Patient Care Advisors and the Clinical Trainers work closely together to support you, to ensure you can correctly use your I-neb.

The Patient Care Advisors will also contact you, when required, to let you know that a new chamber is required for your device. Please do remember If you have any type of issue with your I-neb or questions about its use you can call the number above and speak to one of the Patient Care Advisors.

CLINICAL TRAINERS

If you are new to Promixin and the I-neb, one of the Clinical Trainers will provide the initial training for you. This training will be either face to face in your home or in the hospital; this can also be conducted remotely.

This is dependent on your wishes and the advice of your clinical team. In some cases, your physiotherapist or nurse may prefer to do the training with you themselves.

The Clinical Trainers are also available to answer more complex queries about the I-neb if required. Their role is to ensure you know how to use your I-neb with Promixin and are comfortable in all aspects of its use and care.

I-neb Replacement parts: Ordering and Delivery

The I-nhale Support Programme enables the Patient Care Advisors to manage any replacement parts for you and they will place an order and arrange delivery to you.

This may be via a courier company or Royal Mail. You should receive your replacement parts, usually within two days.

You will be informed as to how your delivery will arrive and when to expect it.

Bionical is registered with the Care Quality Commission (CQC), and the Scottish Care Inspectorate (SCI). The clinical governance framework which is embedded into all Bionical programmes is aligned to all clinical regulatory standards. In addition, Bionical adheres to the Association of the British Pharmaceutical Industry Code and GDPR.

QUALITY OF SERVICE

Our commitment to quality includes the continual review and refinement of our systems.

- We regularly assess our processes and services and ensure we develop our staff to improve standards and outcomes for you, our patient / carer. Your opinions on the Service you have received are important in measuring the quality of the services we deliver, so both you and your doctor will have the opportunity to evaluate the service.
- Throughout your time with us you will be asked to provide feedback on the service that you have received. We review all feedback and make positive changes to ensure our patients are receiving the best possible care. The provision of feedback is not compulsory and if you decline to give feedback please be reassured that the quality of service you receive will not be affected.



QUALITY DEPARTMENT



FAO Quality Assurance Director
Bionical Solutions Limited
The Piazza, Mercia Marina, Findern
Lane, Willington, Derbyshire,
DE65 6DW



Telephone: 01283 753220



Email: Quality@Bionical.com

We will ensure that your comment or complaint is thoroughly investigated and will be acknowledged within 3 working days. We will keep a written record of your comment or complaint with all the details and aim to have the outcome of our investigation completed within 28 days of receipt of your letter.

What if I remain dissatisfied with the Service, is there anyone else I can contact?

Please rest assured the Quality Team we will do all they can to address any complaint in full. However, should you feel that you wish to take this further you can contact any one of the groups on the right as appropriate.

CARE QUALITY COMMISSION (CQC)

CQC National Customer Service
Citygate
Gallowgate
Newcastle upon Tyne NE1 4PA

www.cqc.org.uk

Telephone: 03000 616161

THE NURSING & MIDWIFERY COUNCIL

Complaints Manager
23 Portland Place London
W1B 1PZ

www.nmc.org.uk

Telephone: 020 7637 7181

CARE INSPECTORATE – (SCOTLAND)

Compass House
11 Riverside Drive Dundee
DD1 4NY

www.careinspectorate.com

Telephone: 0345 600 9527

HOW TO CONTACT I-NHALE SUPPORT PROGRAMME



TELEPHONE:
0330 808 8668

EMAIL:
bionical.i-nhale@nhs.net



POST:
I-nhale Support Programme
Bionical Solutions Limited,
The SPA, The Piazza, Mercia Marina,
Findern Lane, Willington,
DE65 6DW

FREQUENTLY ASKED QUESTIONS (FAQ)

Here are some common questions you may have about the service

WHAT WILL HAPPEN WITH MY CONFIDENTIAL INFORMATION?

Your data remain confidential and have been shared with us in order for you to continue to receive the Service. Your confidential information is shared using a secure NHS.net email system and it is stored within secure servers within Bionical and the NHS.

Anonymised and aggregated data about the service shall be shared with Zambon UK Limited for the purposes of service improvements. Please carefully read the Privacy Notice located at the end of this booklet.

DO I HAVE TO PAY FOR THIS SERVICE?

There are no charges to you for the use of this Service.

WHAT DO I DO IF I WISH TO OPT OUT OF THE SERVICE?

If you wish to opt out of the service, then please complete the 'Opt out of Service' Form enclosed. If you ever want to opt out in the future and you cannot find this form, please contact the I-nhale Support Team on 0330 808 8668.

IF I AM NOT HAPPY WITH THE SERVICE, WHAT SHALL I DO?

Our aim is to provide you with an excellent service. Should anything arise that you are not happy with, then please contact the Bionical Quality Department at the address below.

We take all Service complaints seriously and will work to address any issue you may raise. We will also undertake confidential service evaluations to ensure that the Service operates to the highest of standards.

DATA PRIVACY NOTICE



The I-nhale Support Programme is a Patient Support Programme (the "Programme") provided by Bionical Solutions Limited ("Bionical"). I-nhale Support Programme, The Piazza, Mercia Marina, Findern Road, Willington, DE65 6DW, on behalf of Zambon UK Limited, Suite 3, Bicentennial Building, Southern Gate, Chichester, West Sussex PO19 8EZ ("Zambon UK Limited").

Bionical is the organisation that collects your personal information, as described in this Privacy Notice, and will only use your personal information for the purposes of administering the Programme. This information is required for you to participate in the Programme and includes the personal information you voluntarily provide to the Programme, now, or in the future including your name, contact information, gender, date of birth, HCP details and treatment start date. Bionical will also require information on diagnosis, concomitant medication and any medical history.

Bionical will only process the information necessary to:

- Send reminders via call, text, or letter when you need replacement consumables or an I-neb (in case of a fault).
- Obtain feedback regarding your participation in the Programme and assess the performance of the service.
- Provide I-neb training and support.

1. Your personal information will be processed by Bionical for the duration of the Programme and only for the purposes and in the manner described in this document. Bionical maintains appropriate technical and organisational measures to protect your personal information from unauthorised or unlawful access, accidental loss, alteration, or destruction, in accordance with applicable law.

2. Bionical will provide Zambon UK Limited with anonymised information about participation in the Programme for its business purposes (e.g., to learn more about the disease, understand the patient journey). Zambon UK Limited will not have access to your personal information.

3. On a case by case basis and solely for the purposes of pharmacovigilance reporting (collecting information concerning drug or device safety) and safety reasons, Bionical may be required by law to disclose limited identifiable information about you. Zambon UK Limited, as the manufacturer of Promixin is required by law to report safety information to relevant health authorities or to Philips Respironics Drug Delivery UK Ltd, as the CE mark holder of the I-neb, in case of a device incident. In such situations, Bionical may be required to disclose limited information about you (e.g. your age, or date of birth and gender) to the Safety Department of Zambon UK Limited. Such safety reporting may also require Zambon UK Limited to follow up with your doctor to inform him/her about a safety event and to ask for additional medical information, as necessary. Zambon UK Limited shall only process this information for safety reporting purposes. Additionally, you can agree to allow Bionical to provide your full identity (your name and contact information) to the Safety Department of Zambon UK Limited in order to improve the follow-up process with your doctor. For pharmacovigilance (safety) reporting, your information may be transferred to Zambon UK Limited and trusted processors acting on Zambon UK Limited's behalf, located in countries outside of that in which you reside. Zambon UK Limited's Product Safety Privacy Policy, available on their website www.zambonpharma.com/gb/en/, outlines how Zambon UK Limited handles the processing of your personal information when dealing with your safety/side effect report.

4. Transfers of personal information among Zambon UK Limited and its group entities follow applicable laws and our Privacy Policy. For information on these, please visit <http://www.zambonpharma.com/gb/en/>. Transfers to vendors processing personal information under Zambon UK Limited's instructions are made using Model Contracts (Standard Contractual Clauses approved by the European Commission).

Regardless of where your personal information is collected, Zambon UK Limited maintains appropriate safeguards to ensure an adequate level of protection of your information.

Participation in the Programme

1. Is voluntary and free of charge.
2. A decision to not participate will not impact the medical care you receive from your NHS Clinical team. However, if you decide not to agree to the processing of your personal information as described within this document, or you decide to opt out from the available services of the Programme at a later date, you will be unable to participate in, or receive further assistance on the Programme.
3. You can withdraw your consent to participate in the Programme, at any time, without giving any reasons, by notifying Bionical using the contact details provided below.
4. If the Programme ends, your doctor withdraws you from the Programme or you voluntarily withdraw your consent to participate in the Programme, your personal information will be archived. For legal reasons, a copy of your personal data will be kept by Bionical whilst the I-nhale Support Programme is running in the United Kingdom.
5. Should Bionical cease to provide the I-nhale Support Programme in the United Kingdom on behalf of Zambon UK Limited, your personal data held by Bionical will be securely destroyed 8 years from this time. At the end of the Bionical provided service, certain personal information will be returned to Zambon UK Limited and retained as is required by relevant regulations. In some instances, Bionical and/or Zambon UK Limited may be required by law to share personal information with public authorities.

Contact details

1. Please write to I-nhale Support Programme, Bionical Solutions, The Piazza, Mercia Marina, Findern road, Willington, DE65 6DW, or email Bionical.I-nhale@nhs.net if you wish to:

- a. Correct/update your personal information or change/cancel your enrolment in the Programme.
- b. Request access to and receive, a copy of your personal information, or to receive further information on the way we process your data.
- c. Access and rectify information we hold on you as well as request your right to data portability.

2. Your personal information will not be used for any purpose other than the purposes described above in this Privacy Notice.

3. Should you wish to file a complaint regarding the Programme's use of your personal information, please contact the Bionical Data Protection Officer in writing at: Quality Department, Bionical Solutions Limited, The Piazza, Mercia Marina, Willington, Derbyshire, DE65 6DW or via email at Quality@Bionical.com.

4. You can contact your local Data Protection Authority Information Commissioner's Office by visiting <https://ico.org.uk/global/contact-us/> or calling 0303 123 1113.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in the Promixin package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Side effects should also be reported to Zambon UK Limited on +44 (0)800 0288 942 or by email to infoUK@zambongroup.com

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