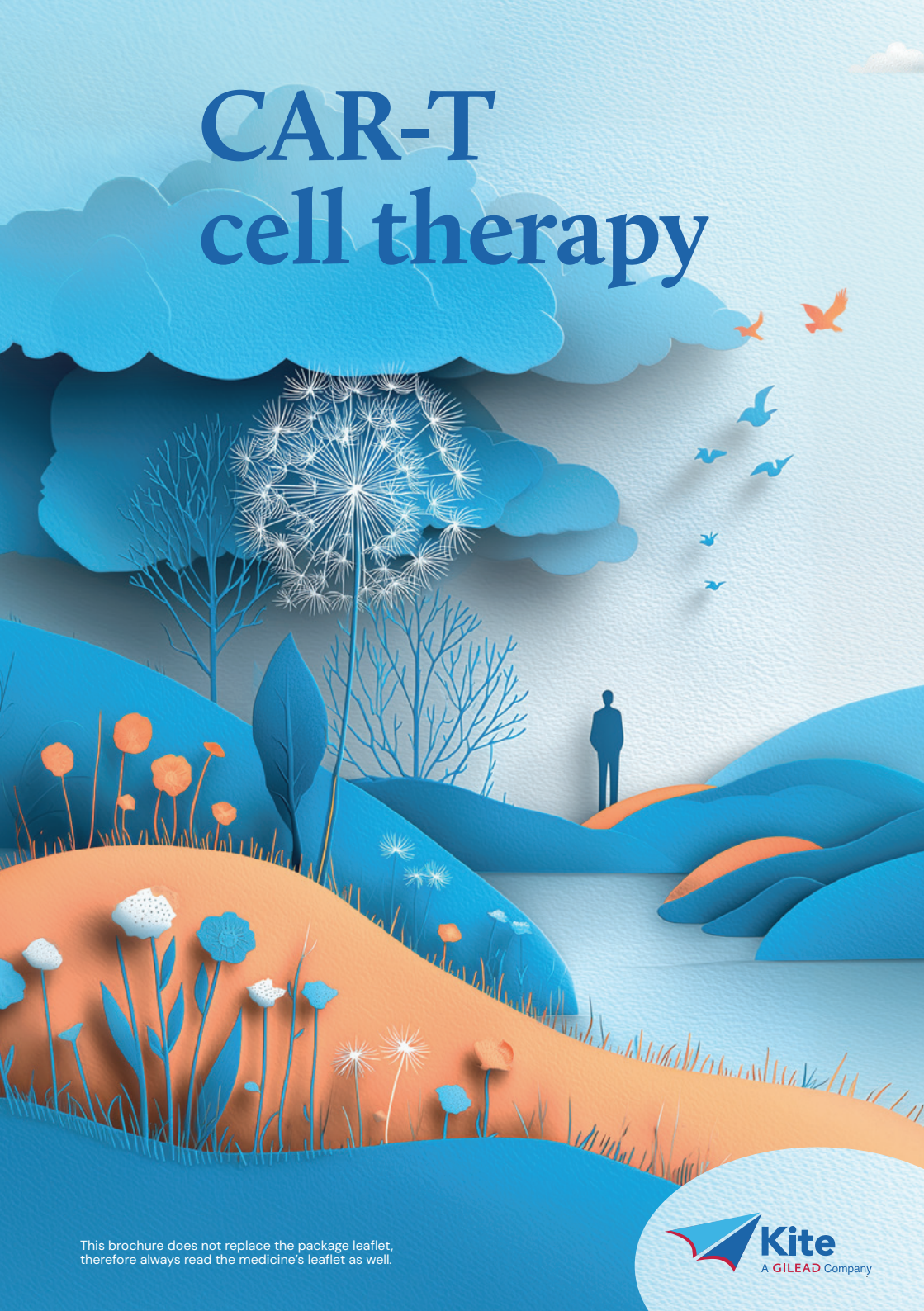
CAR-T cell therapy



This brochure does not replace the package leaflet, therefore always read the medicine's leaflet as well.

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Contents

Treatment goal

Your doctor has suggested treatment with **CAR-T cell therapy**.

This booklet has been specially designed for you and your caregivers **to help you at every stage**: to understand what this treatment involves, how it works and what you can expect along the way.

CAR-T cell therapy is a one-time treatment that uses your own immune cells to fight certain forms of blood cancer. In practical terms, your **T lymphocytes** (a type of white blood cell) are harvested, modified in the laboratory to better recognise and destroy cancer cells, and then infused into your body.

This treatment is often provided after other therapeutic options (such as chemotherapy or certain immunotherapies) have been tried. It adopts a personalised approach, specially engineered to harness your own immune defences.

In this brochure, you will find:
- the key stages of treatment,
- the role of the various professionals who will be supporting you,
- possible side effects and how they are managed,
- practical advice on how best to approach each stage of the process.

This document is designed to guide you every step of the way, so that you hopefully feel informed, supported and confident throughout your treatment.

Understanding your immune system and CAR-T therapy

THE IMMUNE SYSTEM PRODUCES DIFFERENT TYPES OF SPECIALISED CELLS RESPONSIBLE FOR IDENTIFYING AND ELIMINATING AGENTS THAT ARE POTENTIALLY HARMFUL TO THE BODY, SUCH AS VIRUSES, BACTERIA OR CERTAIN ABNORMAL CELLS.[1]

Among them, **T lymphocytes** play a central role in recognising and destroying infected or abnormal cells, including certain cancer cells.[1]

In some situations, tumour cells manage to escape this surveillance. They can modify their surface or produce signals that disrupt recognition by T lymphocytes.[2]

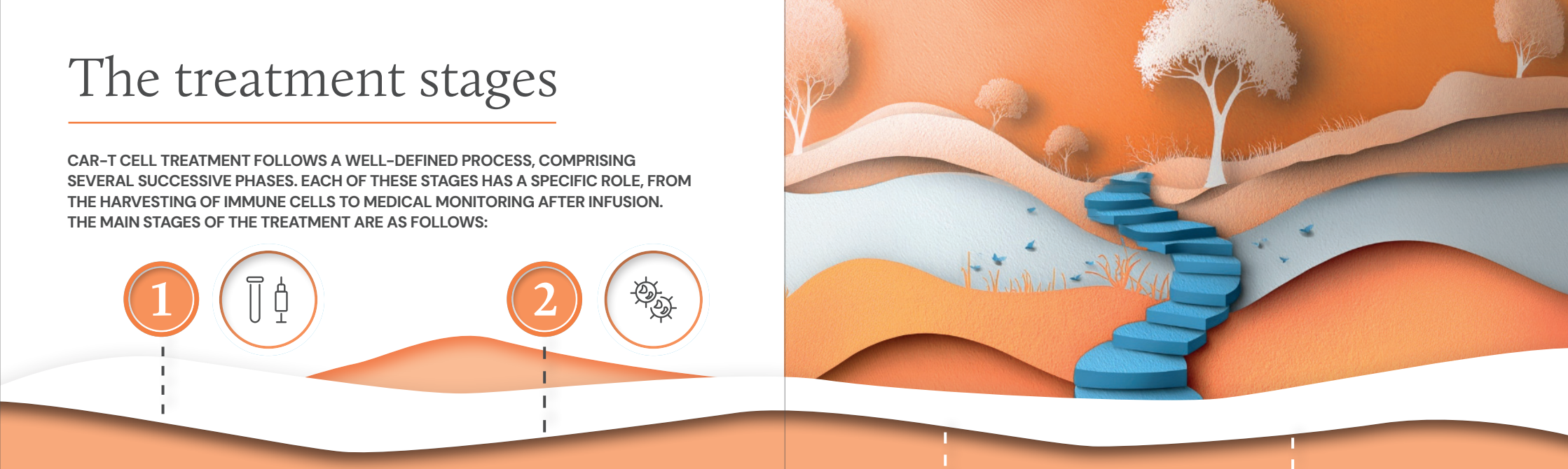
CAR-T *(Chimeric Antigen Receptor T-cells)* therapy is a form of **immunotherapy** that sets out to strengthen this natural response. It harnesses the patient's own T cells, which are harvested and then modified in the laboratory to enable them to recognise a specific target found on the surface of cancer cells.[3]

How it works

- The treatment uses the **body's own immune cells.**[2,3]
- They are modified to **better detect and destroy** cancer cells.[2,3]
- It is a **personalised treatment**, i.e. tailored to each patient.[2,3]

The treatment stages

CAR-T CELL TREATMENT FOLLOWS A WELL-DEFINED PROCESS, COMPRISING SEVERAL SUCCESSIVE PHASES. EACH OF THESE STAGES HAS A SPECIFIC ROLE, FROM THE HARVESTING OF IMMUNE CELLS TO MEDICAL MONITORING AFTER INFUSION. THE MAIN STAGES OF THE TREATMENT ARE AS FOLLOWS:



LYMPHOCYTE HARVESTING
(1 day)[4-6]

- **Confirmation of the indication and verification of criteria**

  The point of this step is to ensure that this treatment is appropriate for your situation and that all the conditions are met for it to be carried out.

- **Pre-harvesting assessment**

  Medical examinations and tests to verify that the cell collection can be performed safely.

- **T lymphocyte harvesting (leukapheresis)**

  Performed in a day-care setting: blood flows through a machine that isolates the necessary cells, and the rest of the blood is immediately re-injected.

  This procedure usually takes between 3 and 6 hours and can be repeated if necessary.

PREPARATION OF THE CAR-T CELLS *(between 2 and 4 weeks)*[4-7]

- **Cells sent to the manufacturing laboratory**

  The harvested cells are transported to a specialised site where they will be prepared.

- **CAR-T cells manufactured**

  The cells are modified and multiplied to recognise and fight cancer cells.

- **Bridging therapy**

  Bridging therapy may be provided to control the progression of the disease while the cells are being manufactured.

- **Return of CAR-T cells and assessment before hospital admission**

  Health check and confirmation that everything is ready for the next stage of treatment.

ADMINISTRATION OF THE CAR-T CELL THERAPY
(2-week hospital stay)[8,9]

During this period, careful observation to quickly detect any adverse effects and intervene if necessary.

- **Preparation (conditioning chemotherapy at -3 days)**

  Treatment over several days to prepare the body to receive CAR-T cells.

- **Infusion of CAR-T cells (“day 0”)**

  Single intravenous administration.

- **Monitoring for min. 7 days**

DISCHARGE FROM HOSPITAL AND REGULAR MONITORING[10]

- **Frequent check-ups after discharge to monitor the effectiveness of treatment and identify any short-, medium-, or long-term complications.**

  Patients must remain near a CAR-T treatment centre for at least 4 weeks after the infusion.

  Close monitoring: first month.

  Intermediate monitoring: between 1 and 3 months.

  Long-term monitoring: beyond 3 months.

Main side effects*

LIKE ANY TREATMENT, CAR-T CELL THERAPY CAN CAUSE SIDE EFFECTS. THEIR INTENSITY AND DURATION VARY FROM PERSON TO PERSON. CLOSE MEDICAL MONITORING IS PROVIDED AFTER THE INFUSION SO THAT ACTION CAN BE TAKEN QUICKLY IF NECESSARY.

1

CYTOKINE RELEASE SYNDROME (CRS)[10,11]

- **What is it?**

An inflammatory reaction linked to the rapid and massive activation of CAR-T cells in the body.

- **When?**

Usually in the days following the infusion.

- **Recognising the signs:** fever, chills, drop in blood pressure, rapid heartbeat, shortness of breath, severe fatigue.
- **Management:** specific medical treatment, hospital monitoring. May require intensive care unit monitoring in some cases.

2

EFFECTS ON THE NERVOUS SYSTEM (NEUROLOGICAL TOXICITIES)[11]

- **When?**

A few days to a few weeks after the infusion.

- **Recognising the signs:** headache, confusion, speech disorders, unusual drowsiness, tremors, convulsions.
- **Management:** close monitoring, appropriate treatment if necessary.

3

TEMPORARY DROP IN BLOOD CELLS[11]

- **Why?**

Treatment may cause a decrease in the number of white blood cells, red blood cells and platelets.

- **Possible consequences:** increased risk of infection, fatigue, shortness of breath, easier bleeding or bruising.
- **Management:** regular blood tests, supportive treatments (transfusions, antibiotics, etc.). Go to the emergency department if you experience fever, chills, prolonged or unusual bleeding, or neurological disorders.

4

HIGHER RISK OF INFECTIONS[11-14]

- **Why?**

The decrease in white blood cells and the treatment itself can weaken the immune system.

- **Possible signs:** fever, chills, cough, pain, burning sensation when urinating, etc.
- **Management**: Prompt treatment with antibiotics or antivirals if necessary, preventive measures. Go to the emergency department if in doubt.

5

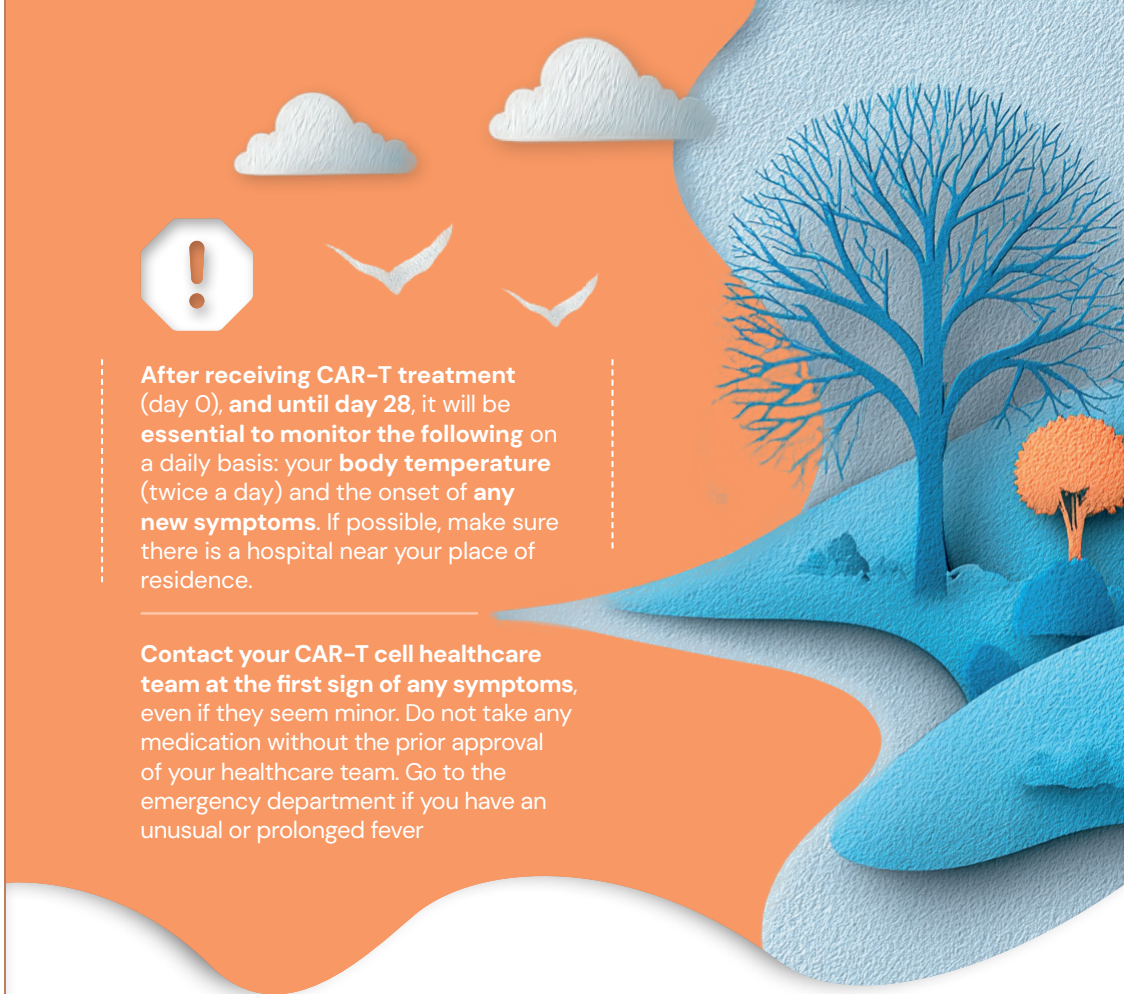
ALLERGIC OR INFUSION-RELATED REACTIONS[11,13,14]

- **Possible signs:** skin rash, itching, shortness of breath, swelling, discomfort during infusion.
- **Management:** immediate treatment with appropriate medication.

* For the full list of side effects please consult the patient information leaflet and/or discuss any concerns with your medical team.

The main side effects according to time of onset[10-14]

IN THE **DAYS OR WEEKS FOLLOWING** INFUSION	**BETWEEN 1 AND 3 MONTHS** AFTER INFUSION	**AFTER 3 MONTHS**
• **Cytokin release syndrome (CRS):** fever, chills, low blood pressure, rapid heartbeat, shortness of breath, extreme fatigue. • **Early neurological disorders:** headache, confusion, speech disorders, unusual drowsiness, tremors, convulsions. • **Allergic or infusion-related reactions:** redness, itching, breathing difficulties, swelling. • **Drop in blood cells:** fatigue, increased risk of infections, easier bleeding.	• **Persistent low blood cells** (white blood cells, red blood cells, platelets). • **Risk of infections still high,** due to the time needed for the immune system to recover. • **Delayed neurological disorders** (less common): memory problems, difficulty concentrating, mood swings.	• **Weakened immunity:** some defences may remain compromised for several months, requiring monitoring and sometimes specific vaccinations. • **Risk of prolonged infections** in some individuals. • **Prolonged drop in blood cells** in rare cases.



After receiving CAR-T treatment (day 0), **and until day 28**, it will be **essential to monitor the following** on a daily basis: your **body temperature** (twice a day) and the onset of **any new symptoms**. If possible, make sure there is a hospital near your place of residence.

Contact your CAR-T cell healthcare team at the first sign of any symptoms, even if they seem minor. Do not take any medication without the prior approval of your healthcare team. Go to the emergency department if you have an unusual or prolonged fever

Good to know

- **Not everyone** experiences side effects.
- If side effects occur, always **inform your healthcare team** immediately.
- An **alert card** will be provided to facilitate treatment in case of an emergency.
- **If in doubt, do not wait**; contact your healthcare team.

My daily routine: useful tips*

CAR-T CELL THERAPY IS A JOURNEY THAT REQUIRES BOTH PATIENCE AND ORGANISATION. BY FOLLOWING A FEW SIMPLE TIPS, YOU CAN FEEL MORE CONFIDENT AT EVERY STAGE: PREPARING FOR YOUR HOSPITAL STAY, TAKING CARE OF YOUR BODY, PROTECTING YOUR IMMUNE SYSTEM, LOOKING AFTER YOUR OWN WELL-BEING AND STAYING IN GOOD SPIRITS. THESE PRACTICAL GUIDELINES HAVE BEEN PREPARED TO HELP YOU IN YOUR DAILY LIFE, FROM THE START OF YOUR JOURNEY TO YOUR RETURN HOME.

a. BEFORE TREATMENT

Preparation is an essential step in ensuring that the CAR-T journey gets off to a good start.

It is recommended that you **gather all relevant medical documents**: recent test results, a complete list of current treatments and contact details for referring doctors. In general it is advisable to be in the best possible condition before starting treatment. This may include prehabilitation measures such as regular physical activity, good nutrition and hydration, as well as psychological support and stress management.

Preparing for admission to hospital helps reduce stress: pack a suitcase with personal belongings, organise certain daily tasks (pets, post, housework, etc.), and identify a loved one who can take over if necessary.

Informing your caregivers about the main stages of treatment ensures you get the support and understanding you need throughout the process.

b. DURING YOUR HOSPITAL STAY

Your stay in hospital is an important part of the CAR-T journey, with several phases of **close monitoring** to ensure safety and comfort.

To reduce the **risk of infection**, it is advisable to limit visits in the days following the infusion.

Bring some **gentle activities** with you – a book, music, etc. Podcasts or small games can help make your stay more enjoyable and keep your mind busy.

It is essential to **report any unusual changes**, such as fever, shortness of breath, confusion, headaches or any sudden change in general condition, so that the team can intervene without delay.

c. AFTER DISCHARGE

Returning home does not mean the end of follow-up care. **Regular consultations and scheduled examinations** remain essential to monitor progress.

Maintaining **enhanced hygiene measures** is important: frequent hand washing, avoiding close contact with sick people or young children due to the increased risk of infection, keeping your environment clean.

Resume activities **gradually**, alternating between rest and gentle occupations, and avoid strenuous effort at first.

It is also recommended that you **do not drive** or operate machinery **for at least 8 weeks after the infusion**, or as long as neurological symptoms persist.

Finally, it is also important to note any symptoms/signs in your diary and discuss them with your healthcare team.

* The content provided does not constitute medical advice. Please discuss any concerns with your medical team.

d. NUTRITION AND HYDRATION

A **healthy diet** helps boost natural defences and aids recovery. Regular hydration is also essential, even if you do not feel thirsty.

Meals should be **varied**: fruit, vegetables, whole grains, protein (meat, fish, eggs, or plant-based alternatives) and dairy products or equivalents.

Certain **dietary precautions** reduce the risk of infection: avoid raw or undercooked meat, fish and eggs, raw milk cheeses and unpasteurised products.

In case of **nausea, diarrhoea or loss of appetite**, opt for small, frequent meals that are easy to digest and not too spicy.

A **nutritionist** can be consulted to help tailor your diet to your individual needs.

e. PSYCHOLOGICAL SUPPORT

CAR-T treatment is an emotionally intense experience.

Taking the time to **express how you feel**, whether to a loved one or a professional, can often reduce stress and make you feel better supported.

A **hospital psychologist** can be present at different stages of the process: during the waiting period, during your hospital stay or even after discharge.

It is also beneficial to cultivate your inner resources: listen to music, read, perform relaxation exercises or participate in activities offered by the hospital such as socio-aesthetics or gentle yoga.

Accepting help from those around you, whether to manage practical matters or simply to rely on their reassuring presence, is a valuable source of support.

Planning regular contact - phone calls, authorised visits - helps to break the isolation and keep your spirits up.

Useful information

THIS SECTION TAKES YOU THROUGH THE RELIABLE CONTACTS AND USEFUL RESOURCES FOR FINDING CLEAR INFORMATION, OBTAINING SUPPORT OR ASKING QUESTIONS ABOUT CAR-T CELL THERAPY AND LYMPHOMA.

a. PATIENT ASSOCIATIONS

Fondation contre le Cancer

Reliable information on cancer, prevention, psychological and social support, activities for patients and their loved ones.

- Telephone Cancerinfo (free): 0800 15 801 (Mon-Fri, 9h-18h)
- Tel. HQ: 02 736 99 99
- E-mail: info@cancer.be
- Website: www.cancer.be

Ligue contre le Cancer

Psychological support, dietary advice, adapted physical activities, socio-aesthetics.

- Free helpline: 0800 940 939
- Website: www.ligue-cancer.net

Anticancer Fund

Scientific information on treatments and personalised support (My Cancer Navigator).

- Tel.: +32 (0)2 268 48 16
- E-mail: info@anticancerfund.org
- Address: Brusselsesteenweg 11, 1860 Meise
- Website: www.anticancerfund.org

Cancer Patients Europe

European association based in Belgium, focused on patient engagement in improving healthcare.

- Website: www.cancerpatientseurope.org

Associations of patients with lymphoma

- Website: www.bhs.be/en/medical-resources-overview/patient-organisations/lymphoma

b. SPECIALIST MEDICAL RESOURCES

European Organisation for Research and Treatment of Cancer (EORTC)

Based in Brussels, coordinates international clinical trials.

- Website: www.eortc.org

Association SFGM-TC (Société Francophone de Greffe de Moelle et de Thérapie Cellulaire)

Technical information and brochures on CAR-T cell treatments and transplants.

- Website: www.sfgm-tc.com

Information Gilead

Web page dedicated to lymphoma and CAR-T

- Website: www.gileadpro.be/fr-be/therapy-areas/expose-lymphoma/treatments

The healthcare team

How can they help?

HAEMATOLOGIST/ONCOLOGIST

Monitors the entire CAR-T treatment process and coordinates key stages (harvesting, manufacturing, packaging, infusion and follow-up). Explains test results, possible side effects and options in the event of complications.

COORDINATING NURSE

Central point of contact throughout the process. Organises appointments, explains the stages involved, answers practical questions, liaises with other parties involved.

NURSE IN THE INPATIENT DEPARTMENT

Ensures daily monitoring after infusion, administers prescribed treatments, monitors vital signs, observes for any side effects and alerts if necessary.

LEUKAPHERESIS TECHNICIAN OR NURSE

Performs T lymphocyte harvesting using the apheresis machine. Explains the procedure and ensures patient comfort throughout the harvesting process (3 to 6 hours on average).

HOSPITAL PHARMACIST

Prepares and monitors associated treatments (conditioning chemotherapy, preventive medication, symptomatic treatments). Provides advice on taking medication at home.

PSYCHOLOGIST

Delivers emotional support to help cope with stress, anxiety, or changes related to treatment. Helps make waiting periods, hospitalisation, and follow-up care more manageable.

Contact details

PHYSIOTHERAPIST

Offers tailored exercises to maintain mobility and muscle strength, combat fatigue and promote physical recovery after treatment.

NUTRITIONIST

Provides advice on nutrition to boost the immune system, manage potential side effects (loss of appetite, digestive issues) and promote recovery.

SOCIAL WORKER

Provides information on available financial and social assistance, helps with administrative procedures (transport, temporary accommodation near the centre, insurance, etc.).

ADDITIONAL SUPPORT

(e.g. socio-aesthetic, relaxation, adapted yoga)

Offered in certain centres, these services help improve overall wellbeing, body image, and stress management during treatment.

My personal and emergency contact details

Main contact person of the CAR-T cell team

- Tel.:
- E-mail:

GP

- Tel.:
- E-mail:

Clinic emergency number

- Tel.:

Contact information of the main caregiver

- Tel.:
- E-mail:
- Address:

My appointments

Date	Time	

Date	Time	

Glossary

- **Antigen:** Substance present on the surface of a cell - normal or cancerous - that can be recognised by the immune system.
- **Bridging therapy:** Temporary treatment given to control the disease while CAR-T cells are being manufactured.
- **CAR-T cells:** Immune cells, called T lymphocytes, are harvested from the patient, modified in the laboratory to recognise a specific target on cancer cells, and then infused.
- **Chimeric receptor (CAR) :** Protein added to T lymphocytes in the laboratory, enabling them to recognise and attack targeted cancer cells.
- **Conditioning chemotherapy:** Short course of chemotherapy administered before CAR-T cell infusion to prepare the body and enable the modified cells to work effectively.
- **Cytokine Release Syndrome (CRS) :** A significant inflammatory reaction that may occur after CAR-T cell activation, causing fever, chills, low blood pressure or shortness of breath.
- **Immunity :** The body's ability to defend itself against microbes and abnormal cells.
- **Immunotherapy:** Treatment that stimulates or strengthens the immune system to help it fight disease, such as certain cancers.
- **Intravenous infusion:** Slow injection of a liquid - medicine, cells, etc - directly into a vein.
- **Leukapheresis:** A blood removal procedure in which a device separates T lymphocytes from the rest of the blood, which is immediately re-injected into the body.
- **Neurological toxicities:** Nervous system disorders that may occur after treatment, such as confusion, headaches or speech disorders.
- **Platelets:** Small blood cells that participate in clotting and stop bleeding.
- **Red blood cells:** Blood cells that carry oxygen to organs and tissues.
- **Side effects:** Adverse reactions that may occur after treatment, such as fatigue, fever or weakened immune system.
- **T lymphocytes:** A type of white blood cell that plays a key role in destroying infected or cancerous cells.
- **White blood cells:** Blood cells that defend the body against infections.

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