LESS342C-W F1H62SXJ2

• You are using the medicines for reasons recommended dose. • You need to take more than the

instructions on the pack, it is unlikely you If you take this medicine according to the How do I know if I am addicted?

provide more information on the safety of By reporting side effects you can help This leaflet was last revised in February 2025. Scheme at: www.mhra.gov.uk/yellowcard side effects directly via the Yellow Card not listed in this leaflet. You can also report

Palarstragerstraße 9 Grassingerstraße 9 Reporting of side effects: If you get any side Wrafton, Braunton, EX33 2DL, United Kingdom Wrafton Laboratories Limited, Exeter Road, The manufacturer is:

enquiries should be sent to this address. Devon, EX33 2DL, United Kingdom and all Omega Pharma Ltd., Wrafton, Braunton, The marketing authorisation holder is

opaque white body, plain on both halves!" capsules, they have an opaque red cap and Packs of Solpadeine Plus Capsules contain 24 quinoline yellow (E 104), gelatin. erythrosine (E 127), patent blue V (E 131), stearate, titanium dioxide (E 171), Other ingredients Maize starch, magnesium Hemihydrate 8 mg and Caffeine 30 mg. Paracetamol 500 mg, Codeine Phosphate Active ingredients Each capsule contains 6. Further information

shown on the pack. Store below 25°C. Do not use this medicine after the 'EXP' date Keep out of the reach and sight of children. Capsules

5. How to store Solpadeine Plus

start taking the medicine again. teel very unwell, but you teel better if you When you stop taking the medicine you other than instructed.

periods of time. You need to take the medicine for longer signs it is important that you talk to your However, if you notice any of the following will become addicted to the medicine.

this medicine. nurse. This includes any possible side effects 83043 Bad Aibling, Germany effects, talk to your doctor, pharmacist or

> paracetamoi (see section 2). ni, (sisobise sollode metabolic acidosis), in portanism grisus sendli eraeves diiw straited, A serious condition that can make blood be estimated from the available data): Frequency "Not known" (frequency cannot Cloudy urine or difficulties urinating.

eyes and skin loss, loss of appetite and yellowing of the Nausea, upset stomach, sudden weight Unexplained bruising or bleeding and aspirin

taking other painkillers such as ibuprofen it you have experienced them before when Breathing problems. These are more likely eniteaws no enitati Skin rash or peeling or mouth ulcers;

such as skin rash and itching Allergic reactions which may be severe drowsiness or restlessness Nervousness, dizziness, irritability, gall bladder removed

and vomiting if you have recently had your Severe abdominal pain, dry mouth, nausea doctor immediately if you experience: Stop taking this medicine and tell your

 Constipation When using this product you may experience: pharmacist or other healthcare professional. effects you should seek advice from your doctor, this medicine. If you have any unwanted side Some people may have side effects when using 4. Possible side effects

see your doctor. confinue or your headache becomes persistent, delayed, serious liver damage. If your symptoms because too much paracetamol can cause this medicine, even if you feel well. This is Talk to a doctor at once if you take too much of

after 3 days, talk to your doctor for advice. than 3 days. If the pain does not improve • This medicine should not be taken for more the risk of severe breathing problems by children below the age of 12 years, due to Solpadeine Plus Capsules should not be taken uncomfortable feeling in the chest difficulty sleeping, shaking and an • Avoid too much caffeine in drinks like coffee

Do not take more than the recommended Do not take more than 4 capsules in 24 hours. Do not take more frequently than every 6 hours. Swallow 1 capsule every 6 hours as needed. Adolescents aged 12-15 years:

Do not take more than 8 capsules in 24 hours. Do not take more frequently than every 6 hours. Swallow 1-2 capsules every 6 hours as needed. Adolescents aged 16 - 18 years: For the elderly a reduced dose may be required. considered if you are underweight (under 50kg) A reduced maximum daily dose should be Do not take more than 8 capsules in 24 hours. Do not take more frequently than every 4 hours. Swallow 2 capsules every 4-6 hours as needed.

Capsules 3. How to take Solpadeine Plus

www.gov.uk/drug-driving-law in the UK may be found here: concerning driving after drugs have been taken Details regarding a new driving offence taking this medicine.

sure whether it is safe for you to drive while Talk to your doctor or pharmacist if you are not It was not affecting your ability to drive safely.

- information provided with the medicine and You have taken it according to the
  - medical or dental problem and The medicine has been taken to treat a

Driving and using machines

offence if: However, you would not be committing an drive if this medicine affects your ability to drive. you know how it affects you. It is an offence to Do not drive while taking this medicine until it may make you sleepy or dizzy. This medicine can affect your ability to drive as

into breast milk and will affect your baby. are breastfeeding. Codeine and morphine passes Do not take Solpadeine Plus Capsules while you birth which may need to be treated. and experience withdrawal symptoms after the bregnancy, your baby may become dependent It you use Solpadeine Plus Capsules during outweigh the potential harm to the baby. the benefits of treatment are considered to you have discussed this with your doctor and pregnant or think you might be pregnant unless Do not take Solpadeine Plus Capsules if you are and tea. High caffeine intake can cause Pregnancy and breast feeding:

morphine toxicity may be worse in these Codeine is not recommended in children with breathing problems, since the symptoms of Use in children with breathing problems: Apnoea Syndrome.

tonsils or adenoids due to Obstructive Sleep children and adolescents after removal of their Codeine should not be used for pain relief in Use in children and adolescents after surgery: Children and adolescents:

from withdrawal symptoms. to your doctor if you think you are suffering spaking, shivering or sweating. You should talk of being sick, diarrhoea, loss of appetite, (palpitations), increased blood pressure, feeling agitation, anxiety, feeling your heartbeat restlessness, difficulty sleeping, irritability, symptoms. Withdrawal symptoms can include stop taking it you may get withdrawal than 3 days. If you become addicted, when you addiction if you take it continuously for more This medicine contains codeine and can cause Possible withdrawal effect:

longer than 3 days. Do not take this medicine continuously for

<u>toxins circulate in the blood leading to organ</u> impairment or sepsis (when bacteria and their pave severe ilinesses, including severe renal Capsules, tell your doctor straight away it you During treatment with Solpadeine Plus interval between doses of your medicine.

gravis which weakens the muscles.

- If you have a condition called myasthenia
- If you are elderly It you weigh less that 50kg
- causes health problems
- If you have a poor diet such that the diet If you are dehydrated
  - If you have glutathione deficiency • If you have haemolytic anaemia
  - αφυλαιοθουσες αφτισιουςλ
- If you have glucose-6-phosphatase affect liver function
- If you are taking other medicines that can non-haemolytic Jaundice)
- It you have Gilbert's Syndrome (familial your doctor that you are sensitive to aspiring
- If you have asthma and have been told by or raised intracranial pressure.
- IT you nave experienced a recent nead injury It you have hypotension or hypothyroidism
- gall bladder. PIT you have had an operation to remove yo
- blockage of your bowel If you have bowel problems including alconolic liver disease

 If you have liver or kidney disease, including Talk to your doctor or pharmacist before taking Warnings and precautions:

respiratory depression.

and gabapentin as there is an increased risk of urgent treatment (see section 2). Pregabalin even from teal (called metabolic acidosis) that must have to a serious risk of blood and fluid abnormality (e.g. probenecid). Flucloxacillin (antibiotic), due you take medicine treat gout and hyperuricemia Capsules at the same time as anticoagulants. If can still take occasional doses of Solpadeine Plus doctor because of the risk of bleeding. But you take a pain reliever on a daily basis, talk to your (anticoagulants e.g. warfarin) and you need to medicines). If you take blood thinning drugs or sedated (e.g. benzodiazepines or related (e.g. sedatives, antidepressants or alcohol) or substances that make you drowsy prescribed for depression in the last 2 weeks (alOAM) evotidini əsebixo ənimeonom

colestyramine (to lower blood cholesterol);

height = 1,43 mm ■ Times New Roman 9p

*TEADING EDGE* LEADING EDGE

**CAPSULES** 

Paracetamol, Codeine, Caffeine

• This medicine is for the short term treatment of acute moderate pain when

other painkillers have not worked. This medicine has been provided to you and should not be given to anyone else.

You should only take this product for a

maximum of 3 days at a time. If you need to take it for longer than 3 days you should see your doctor or pharmacist for advice. This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you

withdrawal symptoms from the medicine when you stop taking it. • If you take this medicine for headaches for Opo not take solpadeine Plus Capsules:

Please read right through this leaflet before you start using this medicine

This medicine is available without prescription, but you still need to use Solpadeine Plus Capsules carefully to get the best results from them. • Keep this leaflet you may need to read it

 If you have any questions, or if there is anything you do not understand, ask your pharmacist

In this leaflet:

1. What Solpadeine Plus Capsules do 2. Check before you take Solpadeine Plus

Capsules 3. How to take Solpadeine Plus Capsules

4. Possible side effects 5. How to store Solpadeine Plus Capsules 6. Further information

Solpadeine Plus
Capsules do
Solpadeine Plus Capsules can be used in patients over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone. They can be used for migraine, headache, dental pain, period pain, strains & sprains,

backache, rheumatic pain and sciatica. The capsules contain three active ingredients; paracetamol, codeine and caffeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Paracetamol is another analgesic to relieve pain. Caffeine acts to further help the effectiveness of paracetamol.

2. Check before you take

**Solpadeine Plus Capsules** This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this medicine. If you take a painkiller for headaches for

more than 3 days it can make them worse.

more than 3 days it can make them worse. • If you have ever had an allergic reaction to paracetamol, caffeine, codeine, other opioid painkillers or to any of the other ingredients (listed in Section 6)

If you are taking other medicines

containing paracetamol or codeine • If you are under 12 years • For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive

sleep apnoea syndrome • If you know that you metabolise very

rapidly codeine into morphine

• If you are pregnant or breastfeeding. • If you have **respiratory depression** or chronic constipation

If you are taking other medicines: Talk to your doctor or pharmacist before taking these capsules if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]);

for information on correct dosages and time Section 3 'How to take Solpadeine Plus Capsules' pharmacist about your treatment. Please refer usppens, you need to speak to your doctor or make you more sensitive to pain. If this Rarely, increasing the dose of this medicine can overdose and/or death. addiction. Overuse and misuse can lead to this medicine), may increase the risk of opioids, such as codeine (an active ingredient of Taking higher doses or more frequent doses of medicine or are becoming addicted to it. becoming tolerant to the effects of this of pain relief, this may mean you are Solpadeine Plus Capsules to get the same level It you feel you need to take more of stopped taking alcohol or drugs anxiety, shaking or sweating, when you have withdrawal symptoms such as agitation,

If you have previously suffered from

illegal substances. objoids, alcohol, prescription medicines, or If you are or have ever been addicted to Solpadeine Plus Capsules: Talk to your doctor or pharmacist before taking

.empetite. teeling or being sick, constipation, lack of breathing, confusion, sleepiness, small pupils, wollade medical advice: slow or shallow on wast stop taking this medicine and seek If you notice any of the following side effects, very high amount of morphine is produced. more likely to get serious side effects because a provide enough pain relief. Other people are produced in very small quantities, and it will not In some people, morphine is not produced or

people in different ways. variation of this enzyme, and this can affect produces pain relief. Some people have a by an enzyme. Morphine is the substance that Codeine is transformed to morphine in the liver (nausea) and being sick (vomiting). deep rapid breathing, drowsiness, feeling sick may include: serious breathing difficulties with flucloxacillin. Symptoms of metabolic acidosis paracetamol is taken together with regular doses for a prolonged period or when these situations when paracetamol is used at abnormality) has been reported in patients in called metabolic acidosis (a blood and fluid flucloxacillin (an antibiotic). A serious condition chronic alcoholism or if you are also taking damage), or you suffer from malnutrition,

Pharmacode Information

**Profile Key** 

Pharmacode Dimensions (NOT TO SCALE)

Pharmacode Positioning

Artwork in this

Text & Print free

area only

Fold line

140mm

140mm



Paracetamol, Codeine, **Caffeine** 

- This medicine is for the short term treatment of acute moderate pain when other painkillers have not
- This medicine has been provided to you and should not be given to anyone else.
- You should only take this product for a maximum of 3 days at a time. If you need to take it for longer than 3 days you should see your doctor or pharmacist for
- This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.
- If you take this medicine for headaches for more than

3 days it can make them worse. Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Solpadeine Plus Capsules carefully to get the best results from them.

- Keep this leaflet you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

#### In this leaflet:

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- 1. What Solpadeine Plus Capsules do
- 2. Check before you take Solpadeine Plus Capsules
- 3. How to take Solpadeine Plus Capsules
- 4. Possible side effects
- 5. How to store Solpadeine Plus Capsules
- 6. Further information

## 1. What Solpadeine Plus Capsules do

Solpadeine Plus Capsules can be used in patients over 12 years of age for the short-term relief of moderate pain that is not relieved by other painkillers such as paracetamol or ibuprofen alone.

. They can be used for migraine, headache, dental pain, period pain, strains & sprains, backache, rheumatic pair and sciatica. The capsules contain three active ingredients; paracetamol, codeine and caffeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain. Paracetamol is another analgesic to relieve pain. Caffeine acts to further help the effectiveness of paracetamol.

## 2. Check before you take Solpadeine Plus Capsules

This medicine contains codeine which can cause addiction if you take it continuously for more than 3 days. This can give you withdrawal symptoms from the medicine when you stop taking it.

This medicine contains paracetamol. Do not take anything else containing paracetamol while taking this

If you take a painkiller for headaches for more than 3 days it can make them worse.

# Do not take Solpadeine Plus Capsules:

- If you have ever had an allergic reaction to paracetamol, caffeine, codeine, other opioid painkillers
- or to any of the other ingredients (listed in Section 6) • If you are taking other medicines containing
- paracetamol or codeine
- If you are under 12 years:
- For pain relief in children and adolescents (0-18 years of age) after removal of their tonsils or adenoids due to obstructive sleep apnoea syndrome

  If you know that you metabolise very rapidly codeine
- into morphine
- If you are pregnant or breastfeeding.
- If you have respiratory depression or chronic constipation

### If you are taking other medicines

Talk to your doctor or pharmacist before taking these capsules if you are taking any prescribed medicines; particularly metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick]); colestyramine (to lower blood cholesterol); monoamine oxidase inhibitors (MAOIs) prescribed for depression in the last 2 weeks or substances that make you drowsy (e.g. sedatives, antidepressants or alcohol) or sedated (e.g. benzodiazepines or related medicines). If you take blood thinning drugs (anticoagulants e.g. warfarin) and you need to take a pain reliever on a daily basis, talk to your doctor because of the risk of bleeding. But you can still take **occasional** doses of Solpadeine Plus Capsules at the same time as anticoagulants. If you take medicine treat gout and hyperuricemia (e.g. **probenecid**). **Flucloxacillin** (**antibiotic**), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2). Pregabalin and gabapentin as there is an increased risk of respiratory depression.

## Warnings and precautions:

Talk to your doctor or pharmacist before taking this

- If you have liver or kidney disease, including alcoholic liver disease
- If you have bowel problems including blockage of
- your bowel

  If you have had an operation to remove your gall bladder.
- If you have hypotension or hypothyroidism
- If you have experienced a recent head injury or raised intracranial pressure.
- If you have asthma and have been told by your doctor that you are sensitive to aspirin.
- If you have Gilbert's Syndrome (familial
- non-haemolytic jaundice)
- If you are taking other medicines that can affect liver function
- If you have glucose-6-phosphatase dehydrogenase deficiency
- If you have haemolytic anaemia
- If you have glutathione deficiency
- If you are dehvdrated
- If you have a **poor diet** such that the diet causes health problems
- If you weigh less that 50kg
- If you are elderly
- If you have a condition called myasthenia gravis

which weakens the muscles.

They may reduce your dose or increase the time interval between doses of your medicine.

During treatment with Solpadeine Plus Capsules, tell your doctor straight away if you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition. chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being

Codeine is transformed to morphine in the liver by an enzyme. Morphine is the substance that produces pain relief. Some people have a variation of this enzyme, and this can affect people in different ways. In some people, morphine is not produced or produced in very small quantities, and it will not provide enough pain relief. Other people are more likely to get serious side effects because a very high amount of morphine is produced. If you notice any of the following side effects, you must stop taking this medicine and seek mmediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.

Talk to your doctor or pharmacist before taking Solpadeine Plus Capsules:

- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal substances.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or
- If you feel you need to take more of Solpadeine Plus Capsules to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it.

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Taking higher doses or more frequent doses of opioids, such as codeine (an active ingredient of this medicine), may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor or pharmacist about your treatment. Please refer Section 3 'How to take Solpadeine Plus Capsules' for information on correct dosages and time intervals.

Do not take this medicine continuously for longer than 3 days.

Possible withdrawal effect: This medicine contains codeine and can cause addiction if you take it continuously for more than 3 days. If you become addicted, when you stop taking it you may get withdrawal symptoms. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling of being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. You should talk to your doctor if you think you are suffering from withdrawal symptoms.

## Children and adolescents

Use in children and adolescents after surgery: Codeine should not be used for pain relief children and adolescents after removal of their tonsils or adenoids due to Obstructive Sleep Apnoea Syndrome.

Use in children with breathing problems: Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children.

### Pregnancy and breast feeding:

Do not take Solpadeine Plus Capsules if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Solpadeine Plus Capsules during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Solpadeine Plus Capsules while you are breastfeeding. Codeine and morphine passes into breast milk and will affect your baby.

## Driving and using machines

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

Do not drive while taking this medicine until you know how it affects you. It is an offence to drive if this medicine affects your ability to drive

However, you would **not** be committing an offence if: • The medicine has been taken to treat a medical or

- dental problem and You have taken it according to the information
- provided with the medicine and
- It was not affecting your ability to drive safely. Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this

Details regarding a **new driving offence** concerning driving after drugs have been taken in the UK may be found here: www.gov.uk/drug-driving-law

# 3. How to take Solpadeine Plus Capsules

medicine.

Swallow 2 capsules every 4-6 hours as needed. Do not take more frequently than every 4 hours. Do not take more than 8 capsules in 24 hours. A reduced maximum daily dose should be considered if you are underweight (under 50kg) For the elderly a reduced dose may be required.

## Adolescents aged 16 - 18 years: Swallow 1-2 capsules every 6 hours as needed.

Do not take more frequently than every 6 hours. Do not take more than 8 capsules in 24 hours.

#### Adolescents aged 12-15 years: Swallow 1 capsule every 6 hours as needed. Do not take more frequently than every 6 hours.

- Do not take more than 4 capsules in 24 hours. Do not take more than the recommended dose Avoid too much caffeine in drinks like coffee and tea.
- High caffeine intake can cause difficulty sleeping, shaking and an uncomfortable feeling in the chest Solpadeine Plus Capsules should not be taken by
- children below the age of 12 years, due to the risk of severe breathing problems This medicine should not be taken for more than
- 3 days. If the pain does not improve after 3 days, talk to your doctor for advice.

Talk to a doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. If your symptoms continue or your headache becomes persistent, see your doctor.

## 4. Possible side effects

Some people may have side effects when using this medicine. If you have any unwanted side effects you should seek advice from your doctor, pharmacist or other healthcare professional

When using this product you may experience: Constipation

Stop taking this medicine and tell your doctor immediately if you experience:

- Severe abdominal pain, dry mouth, nausea and vomiting if you have recently had your gall bladder removed
- Nervousness, dizziness, irritability, drowsiness or restlessness
- Allergic reactions which may be severe such as skin
- Skin rash or peeling or mouth ulcers; itching or
- sweating Breathing problems. These are more likely if you have experienced them before when taking other
- painkillers such as ibuprofen and aspirin Unexplained **bruising** or **bleeding**
- Nausea, upset stomach, sudden weight loss, loss of appetite and vellowing of the eyes and skin Cloudy urine or difficulties urinating.

Frequency "Not known" (frequency cannot be estimated from the available data): A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

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 this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

## How do I know if I am addicted?

If you take this medicine according to the instructions on the pack, it is unlikely you will become addicted to the medicine. However, if you notice any of the following signs it is important that you talk to your

- You need to take the medicine for longer periods of time.
- You need to take more than the recommended dose. You are using the medicines for reasons other than
- instructed. When you stop taking the medicine you feel very unwell, but you feel better if you start taking the medicine again

# 5. How to store Solpadeine Plus Capsules

Keep out of the reach and sight of children. Do not use this medicine after the 'EXP' date shown on the pack. Store below 25°C.

# 6. Further information

Active ingredients Each capsule contains Paracetamol 500 mg, Codeine Phosphate Hemihydrate 8 mg and

Other ingredients Maize starch, magnesium stearate, titanium dioxide (E 171), erythrosine (E 127), patent blue V (E 131), quinoline yellow (E 104), gelatin.

Packs of Solpadeine Plus Capsules contain 24 capsules, they have an opaque red cap and opaque white body, plain on both halves. The marketing authorisation holder is Omega Pharma

Ltd., Wrafton, Braunton, Devon, EX33 2DL, United Kingdom and all enquiries should be sent to this address. The manufacturer is Wrafton Laboratories Limited,

Exeter Road, Wrafton, Braunton, EX33 2DL, United

Kingdom or Swiss Caps GmbH Grassingerstraße 9 83043 Bad Aibling, Germany (Aenova Group). This leaflet was last revised in February 2025.

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