



# Ramadan Expert opinion interview: Focus on Gliclazide

## **Strategies for Ramadan:**

Diabetes Experts Share Their Insights

**Who Should Refrain from Fasting? How One Doctor Decides Which Patients Can Fast**

**Diamicron MR 60®: Why It Is the Preferred Choice**

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How One Diabetic Patient Participates in the Ramadan Fast



# Ramadan Expert opinion interview: Focus on Gliclazide

## Diabetes Experts Share Their Strategies for Ramadan

The approach of Ramadan is an occasion for Muslim diabetics and their healthcare providers to prepare for the challenges of a daylong fast during one of the hottest seasons of the year. What are the best ways to do that? What in practical experience works best for Ramadan preparations? In this newsletter, three diabetes experts share their insights into proven ways to provide a high level of care to patients during Ramadan.

## How One Doctor Determines Who Can Take On the Ramadan Fast

Khaled Tayeb, MD, a consulting diabetologist at the Saudi Arabia Ministry of Health in Riyadh, has a protocol he follows in determining whom he thinks can safely take on the Ramadan fast:

- Regarding Ramadan, provided a type 1 patient has been educated and has medical support, and knows what precautions to take, can fast.
- A very elderly person, especially if he lives alone, of course fears hypoglycemia. In that case we may tell him not to fast. But if he has no renal, or heart, or liver problems, is in relatively good health, and has a family that is in close contact with him, then he may fast. We determine this case by case.
- A pregnant woman who is on insulin therapy should not fast. A woman with gestational diabetes, if properly treated, can fast. A lactating woman who feels she cannot fast can refrain from fasting.

He recommends that patients test their blood glucose level at least five times in every 24-hour period: Before the sunset meal and two hours after; before the dawn meal and two hours after; and at midday to monitor their blood glucose levels during the daylong fast.

## Why Diabetes Experts Prefer Diamicron MR 60®

Since its introduction, **Diamicron MR 60®** (gliclazide) has been consistently rated as the most effective sulfonylurea on the market (see Comparison Studies below).<sup>1-6</sup> It poses the least danger of causing hypoglycemia among its drug class. “Diamicron MR 60® modified-release tablet, is our preferred choice for a sulfonylurea during Ramadan,” says Dr. Tayeb. “It’s safe and easy to use during Ramadan, and it’s simple to use because

it’s a one-time-per-day dose that can be taken during the Iftar time, the evening meal. It is our preferred sulfonylurea for patients participating in the Ramadan fast.”

“This is evidence-based; a lot of studies have shown that the prevalence of hypoglycemia among patients with type 2 diabetes who fast during Ramadan and use **Diamicron MR 60®** is similar to the prevalence of hypoglycemia among patients who use DPP-4 inhibitors.<sup>1-6</sup> That means there’s a very low prevalence of hypoglycemia among **Diamicron MR 60®** patients. Users experienced the least number of hypoglycemic episodes among patients taking a sulfonylurea.

Afaf Alshammary, MD, a consultant in endocrinology and diabetes at the King Abdulaziz Medical City in Riyadh, says her clinic prescribes **Diamicron MR 60®**. “After metformin, sulfonylurea is the next step. In the past we were using glibenclamide but changed over to **Diamicron MR 60®**. Compared to the glibenclamide, I can see that hypoglycemia definitely is not a major concern among **Diamicron MR 60®** users. Another thing is that if a patient’s blood sugar has not been controlled after primary treatment with metformin, when **Diamicron MR 60®** is added to metformin it works quickly and strongly to reduce HbA1c.”

Dr. Alshammary adds that typically when a patient is started on insulin, the usual next step is to stop prescribing a sulfonylurea. “However, patients and I have often observed the same thing: They are reluctant to stop taking **Diamicron MR 60®**. They’ll say, ‘Doctor, when I stop the **Diamicron MR 60®**, my blood sugar is wacky. It’s not as controlled as it’s supposed to be. It seems my blood is better when I use **Diamicron MR 60®**.’ And I see it too, so while I might have stopped prescribing **Diamicron MR 60®** for them, I’ll resume it. When we add basal insulin to the **Diamicron MR 60®** and metformin they had been taking before, their highs and lows are more stable.”

Both Saudi doctors cited the studies below—particularly the ADVANCE study and two studies led by Dr. Saud Al Sifri<sup>2,3,6,7</sup>—that over the years have proven **Diamicron MR 60®**’s distinctly superior efficacy compared with other sulfonylureas.

“Another of **Diamicron MR 60®**’s virtue is that it is inexpensive,” says Amy Hess-Fischl, MS, RD, LDN, BC-ADM, CDE, program coordinator for the Teen and Adolescent Diabetes Transition Program at the University of Chicago’s Kovler Diabetes Center in Illinois, United States. “And that’s one reason why you see it used around the world, especially in the Middle East, because the market is affordable.”



“You can certainly put a positive spin on **Diamicron MR 60**<sup>®</sup> because of its low cost. I’m very aware of the cost of medications and deal with that every single day,” says Ms. Hess-Fischl. “It’s very difficult for me with a clear conscience to recommend a product that a patient cannot afford. **Diamicron MR 60**<sup>®</sup> is an affordable option for patients. While it may not have the highest risk of hypoglycemia as with other shorter-acting sulfonylureas, taking it requires that the individual using it adjusts the dose timing according to whether they are fasting or not.”

“Diamicron MR 60<sup>®</sup>’s modified-release tablet is our preferred choice for a sulfonylurea during Ramadan.”

– Khaled Tayeb, MD

Dr. Tayeb also touts **Diamicron MR 60**<sup>®</sup>’s low cost. “When you compare other classes of drugs that are very expensive for patients to afford, the gliclazide/metformin free combination is an excellent choice for them.”

Dr. Alshammary likes the ability to optimize **Diamicron MR 60**<sup>®</sup> doses. “If a patient who has begun talking gliclazide is still not controlled within one to two weeks, we can easily optimize the dose.”

Dr. Tayeb follows international protocol when starting a newly diagnosed patient with type 2 on diabetes medication. “Of course, the first drug we prescribe is metformin. If, however, a patient cannot tolerate metformin or there is any counter-indication to it, the next treatment is a sulfonylurea. International guidelines recommend sulfonylurea as the next step, and **Diamicron MR 60**<sup>®</sup> is our preferred sulfonylurea.”

“If a patient who is already taking metformin and **Diamicron MR 60**<sup>®</sup>—our first line of treatment—needs to establish more control over his blood sugar levels, we will add a basal insulin while continuing to have him take metformin/gliclazide.”

## Preparing for Ramadan: Patient Education

Diabetes healthcare providers agree that preparing patients for Ramadan should start several weeks before the fasting month. “We start educating patients three months, even four months, before Ramadan,” says Dr. Alshammary. “This gives us and them enough time to understand how Ramadan fasting can affect them, and what they have to do to prepare for it. So, while they are seeing their physicians, they are also seeing their diabetes educator and dietitian as well. We tailor our Ramadan advice according to the patient’s lifestyle, age, and comorbidities.”

“Education is the main factor in the successful outcome of patients dealing with diabetes during Ramadan,” says Dr. Tayeb. (Dr. Tayeb’s diabetes center, one of the first of its kind in Saudi Arabia, treats 18,000 patients.) “We prefer that patients get involved in what we call a Structured Diabetes Education, which may also involve relatives and other healthcare professionals. They should know that fasting involves changes in their lifestyle, meal timing, dosages of their medicines, and what to do when problems arise, such as low or high blood glucose while fasting. Studies have shown that educating patients before Ramadan reduces the occurrence of hypoglycemia in these patients by almost 50 percent.”<sup>8-12</sup>

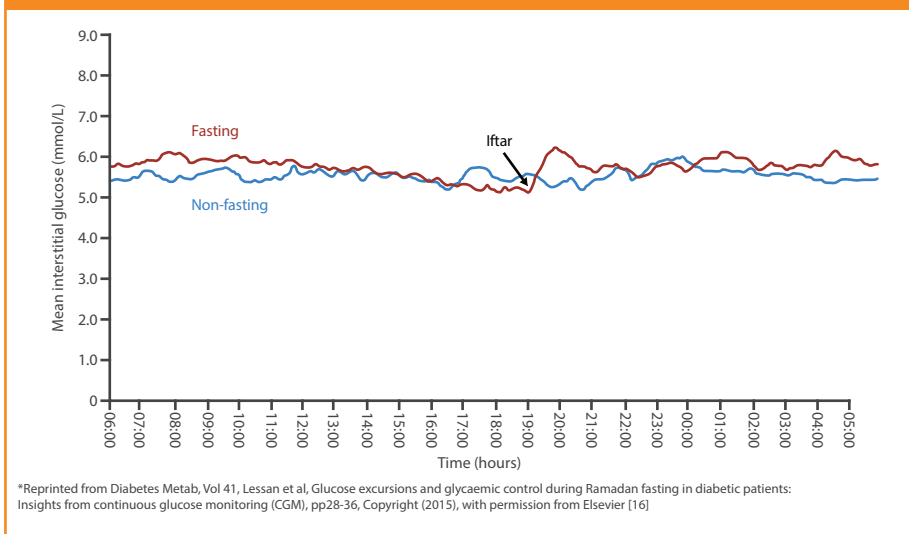
“We start educating patients three months, even four months, before Ramadan. This gives us and them enough time to understand how Ramadan fasting can affect them, and what they have to do to prepare for it.”

– Afaf Alshammary, MD

## Good Patient Education Key to Safe Ramadan Fasting

A crucial aspect of good patient education is the availability of literature across several channels: pamphlets, website, videos, private

Mean continuous glucose monitoring (CGM) profiles from healthy subjects before and during Ramadan; there is a remarkable stability of blood glucose during fasting hours followed by a minimal rise in blood glucose at iftar\*



Source: Diabetes and Ramadan: Practical Guidelines. International Diabetes Federation.<sup>14</sup>



TV channels.<sup>13,14</sup> “We make sure that we have literature in inpatient and outpatient waiting areas—not just in our diabetes center but throughout the entire medical center,” says Dr. Alshammary. “They can also drop by to visit educators, and some of the educators have provided their email addresses. Patients can shoot them an email if they have some questions.”

## Ramadan Food and Hydration

Dr. Tayeb encourages his diabetic patients to experiment with fasting before Ramadan. “We ask patients who intend to keep the Ramadan fast to conduct a trial fast, say, two weeks before Ramadan. They try to fast three days and track their blood glucose levels before and after the fast to see the effects of fasting and whether it works for them.”

“Unfortunately, many patients consume large quantities of carbohydrates at the sunset meal, which can lead to hyperglycemia. So we advise them to distribute their calories throughout the non-fasting hours. They should avoid sugary foods, and to try to consume food that contains fiber.”

“Also, very important, they should drink a lot. One of the complications that can occur with diabetics during Ramadan, aside from hypoglycemia or hyperglycemia, is dehydration. So our advice is to drink a lot of non-sugary fluids as much and as often as they can.”

Ms. Hess-Fischl notes that Ramadan is a family event. “At Iftar people sit with their family members and eat,” she says. “So you have to work with a patient’s family and advise them: Don’t serve juice; try to limit dates to two each; and make sure that you’re serving more vegetables than usual. Our baseline recommendation is to not overdo the amount of carbohydrates anybody consumes at Iftar.”

## Testing Before and During Ramadan

Dr. Alshammary conducts routine medical tests before Ramadan: fasting blood sugar and renal profiles, HbA1c levels; lipid profile; and blood pressure. “These are nothing exceptional, but we stress glucose monitoring at home for diabetic patients, and we make sure that they are bringing their blood sugar readings with them to the clinic.”

The onset of Ramadan, says Ms. Hess-Fischl, “creates the need to test during the day, mid-day, in the afternoon, right before Iftar and then after Iftar, as well as testing again anytime that there are symptoms.”

## The Ramadan Exemption

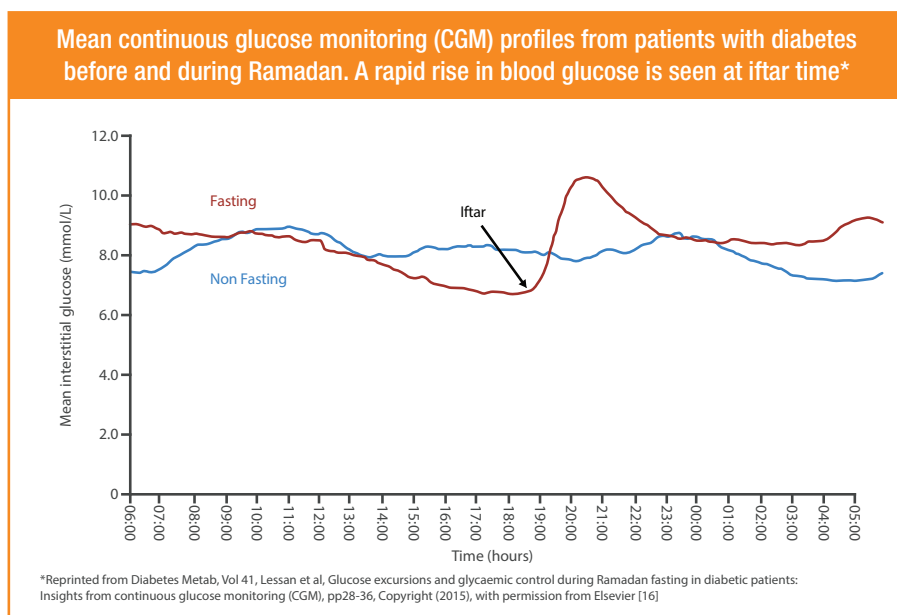
A very common aspect of treating diabetic patients is dealing with their desire to fast during Ramadan even though the Qur’an offers an explicit exception to Muslims who are in ill health: They do not have to fast and there is no shame or penalty for not doing so. “One of the challenges here is patients who insist on fasting even though they are clearly eligible to be among those who can be exempted,” says Dr. Alshammary. “In that case, we usually will talk to a patient’s family, especially if they’re teenagers or in an even younger age group. So their parents come to the clinic

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– Khaled Tayeb, MD

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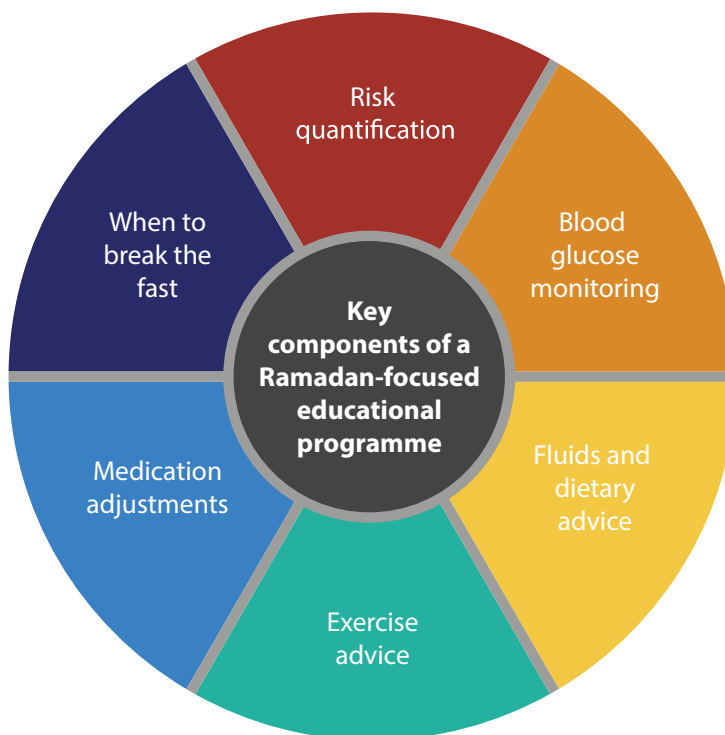
– Amy Hess-Fischl, MS, RD, LDN, BC-ADM, CDE



Source: Diabetes and Ramadan: Practical Guidelines. International Diabetes Federation.<sup>14</sup>



## Key components of a Ramadan-focused educational programme



Source: Diabetes and Ramadan: Practical Guidelines. International Diabetes Federation.<sup>14</sup>

with them, where I can discuss the exemption, but sometimes they don't like to have this information. They'll say that they already know how to manage hypoglycemia, which means they want their child to go ahead with the fast. On the other hand, we see the occasion as an opportunity to give the whole family advice on how to observe their diet, exercise, and fluids during the month of fasting."

### Difficult and High-Risk Patients

Every diabetes practice has to deal with high-risk patients. For Dr. Alshammary, these are patients with HbA1c levels of 11 or 12 who do not respond well to instruction. "We respond by giving priority access to see the educator not only just before Ramadan but also on a weekly basis." The hope is that getting personalized education before Ramadan will help those patients move safely through Ramadan. "If their blood sugar is not controlled before Ramadan, actually we optimize the dose just the visit before Ramadan."

Even though they are exempt from fasting during Ramadan for reasons of health, the majority of diabetic patients in the Kingdom of Saudi Arabia undertake the fast.<sup>12</sup> Although most of them are aware of the risks, they still choose to observe the fast. "Although diabetics are exempt, that does not persuade them," says Ms. Hess-Fischl. "So it is very important to acknowledge and reach out to prepare these people as much as possible for Ramadan."

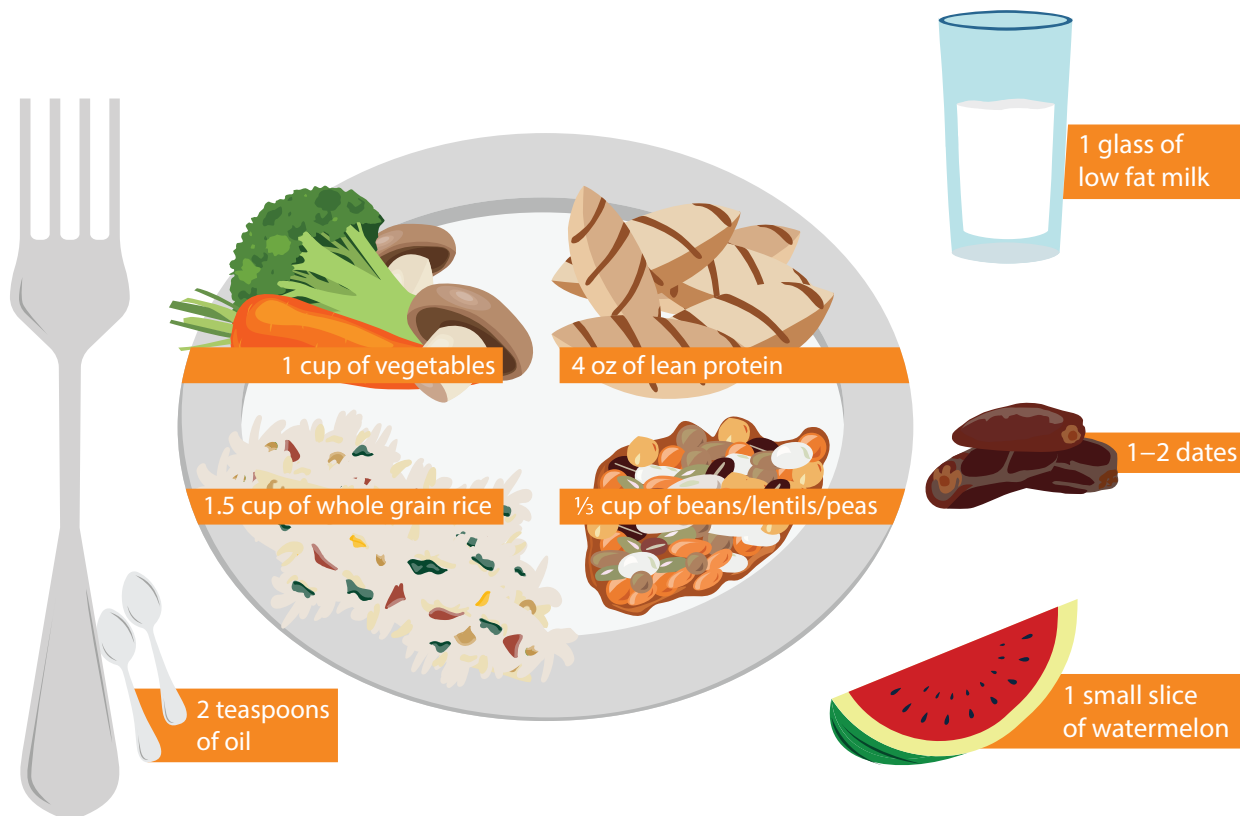
Dr. Alshammary thinks the most challenging task during Ramadan is to avoid the acute complications that can arise due to altered meals, activities, and sleep patterns. "The long hours of fast combined with hot, dry weather puts our patients at higher risk compared to Muslims fasting in other parts of the world. So our two main concerns are hypoglycemia and hyperglycemia. Another is the timing—what time of day to take medications? Exercise is another issue. What time is best for it? How frequently should you check blood sugar and when? When should you break the fast? Patients already know that if they check their blood sugar and it's low, they should break the fast immediately. There is no question about it."

Dr. Tayeb says that some patients will not follow the advice to break the fast when symptoms of hypoglycemia appear. "Unfortunately, there are some who continue fasting, even though we've taken time to educate them that they do not have to prolong the fast if it creates a clear danger to them. Another misconception we see among some patients is their belief that if they shed blood while testing their blood glucose, it invalidates their fast. This is not true; it's an incorrect belief. We

One of the common mistakes patients can make is not responding quickly to symptoms of hyperglycemia or hypoglycemia. ... If there's hypo- or hyperglycemia, *break the fast.*"  
– Khaled Tayeb, MD



## Example of a Ramadan plate\*



This meal provides: 770 kcal, 45% carbohydrate, 20% protein and 35% fat

\*Plate to be adapted according to the individual's daily caloric target

Source: Diabetes and Ramadan: Practical Guidelines. International Diabetes Federation.<sup>14</sup>

always tell them they can test their blood glucose as many times as they need without compromising the Ramadan fast. Also, one of the common mistakes patients can make is not responding quickly to symptoms of hyperglycemia or hypoglycemia. The first calls for insulin, while the second calls for eating right away. If there's hypo- or hyperglycemia, break the fast."

Dr. Alshammary often sees patient misperceptions about diabetes educators. "Some of our type 2 patients are elderly and their education is not optimum, so sometimes when they deal with diabetes educators they don't listen or follow advice. So they'll ask to see the physician. The problem there is that we don't have the time to spend with them because so much has to be allocated among many patients. Result: Patient education time becomes shorter and shorter."

## The IDF 2017 Ramadan Guidelines

Ms. Hess-Fischl strongly recommends reading the International Diabetes Federation's 2017 Ramadan guidelines.<sup>13</sup> "They give a good overview of the dosage adjustments needed for Ramadan. They break down information by medication, so it will say that if you're on metformin, this is what you need to do. Or if you're taking TZDs, or sulfonylureas, or GLP-1 RAs, or DPP-4s, or insulin. They are very good at spelling out exactly what to do with each medication. They also address the need for increased blood glucose monitoring during Ramadan. The 2017 guidelines are a great improvement over the IDF's 2015 Ramadan guidelines, which were not as specific or detailed."



## The Patient's Voice



Mr. Ahmad, a type 2 diabetic who lives in Jeddah, is an example of how patients should adapt to having diabetes, by taking medication on time with good diet and exercise—the standard and proven way to manage type 2 diabetes.

Mr. Ahmad was first diagnosed with type 2 diabetes at the age of 48. “At the time I was diagnosed, I was a bit obese. While I had weighed 70 kilograms when I got married, lots of travel and work led me to gain 25 kilograms.”

### How Diabetes Influences His Lifestyle

Regarding the food intake routine, Mr. Ahmad stated, “that was a wake-up call for me. I modified my food intake and began exercising.” He highlighted that he eats three meals a day, but two of them are small, “breakfast is coffee plus three dates, lunch is normally my main meal, and dinner is fruit or snacks.” He said he keeps a balance between eating and exercise. For the past few years, he has been walking more often and maintaining good glucose control.

Mr. Ahmad started taking Diamicon MR® almost 20 years ago, right after his diagnosis. “I started with the 60 mg dose and for the past five years now take two tablets of Diamicon MR 60®. In addition to another treatment, mainly added at my main meal, but no insulin.” And Mr. Ahmad’s doctor confirmed that, “there was no reason to modify treatment and his HbA1c is 6.8% matching target.”

“I have never had a case of hypoglycemia in the past 20 years. Staying balanced in my habits has saved me from experiencing any dramatic developments or disease complications. That’s what has brought me down from 100 kilograms to now 82 kilograms. And I expect after Ramadan it will be 80.”

“Personally, I believe in reading materials dedicated for diabetic patients either online or in waiting areas at my doctor’s office.

This has helped me big time with understanding the disease. I do expect more of these educational instructions from doctors and expect doctors to spend some time to give advice to patients in the clinic. I recommend that all diabetic patients ask their physician for advice and allocate more time for understanding their disease.”

### How Diabetes Affects His Participation in Ramadan

“I have fasted during Ramadan without fear for the past 20 years, thanks to the successful medication I take and lifestyle modification I do.” Today, Mr. Ahmad weighs 82 kilograms, “for the past 10 years, I usually start the fast weighing 82 kilograms, then finish at 80.” He eats less and has learned to linger for a long time over one sweet treat rather than consume a whole lot of them.

Based on his doctor’s recommendation, the time to take Diamicon MR 60® had been switched from morning to evening (Iftar time) during Ramadan. “So I will switch the time to just after sunset. My family and I make the evening meal light, and then consume a heavier meal before sunrise.”

Among Mr. Ahmad’s friends and business contacts who are diabetic patients and who are taking alternative treatments, many, he noticed, had difficulties with hypoglycemia and sugar control, especially in Ramadan. “That’s why a combination of the right treatment and lifestyle modification is needed in Ramadan.”

Mr. Ahmad said, “Since I’ve been stable and controlled for the past years, the majority of my blood glucose checks are just before and two hours after breakfast. Since then, unless I don’t exercise or my schedule is unusual, I may check my levels twice a week, regarding the HbA1c I do once a month. “ Mr. Ahmad concluded that, “at my age, if I keep to my diet and exercise routines, my blood glucose levels and weight stay very much the same. I’ve learned to eat less and be smart.”

Mr. Ahmad, now 69 years old, is planning to fast for Ramadan 1439 as usual, with good health and peace of mind, thanks to effective sugar control and lifestyle modification.

## Recommended Ramadan Practices

- Create an individualized plan for Ramadan for each diabetic patient.
- Make it easy for patients to access Ramadan-related literature, website content, and other educational media.
- Make it easy for patients to contact diabetes educators at specific times of the day and week.
- Have patients experiment with fasting for three days two weeks before Ramadan.
- Advise patients to spread their calories, particularly carbohydrates, through the non-fasting hours of Ramadan.
- Because the majority of diabetic patients observe the Ramadan fast even though they are not obligated to, treatment plans for Ramadan should be designed to counteract the effects of heavy Iftar meals. This can include switching drug dosage times, increasing the number of daily blood glucose checks.
- Remind patients that along with hypoglycemia and hyperglycemia dehydration can be a major cause of problems during Ramadan.
- Older, less educated patients can be difficult to persuade to change their habits during Ramadan. This is a good time to involve their families or caregivers in helping them through Ramadan.
- Advise patients to make sure they take their medications at the right time during Ramadan.



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## Ramadan Newsletter Contributors



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•**COMPOSITION\*** Diamicon 60 mg MR, modified release tablet containing 60 mg of gliclazide, contains lactose as an excipient. •**INDICATION\*** Non insulin-dependent diabetes (type 2) in adults when dietary measures, physical exercise and weight loss alone are not sufficient to control blood glucose. •**DOSAGE AND ADMINISTRATION\*** One half to 2 tablets per day i.e. from 30 to 120 mg taken orally as a single intake at breakfast time, including in elderly patients and those with mild to moderate renal insufficiency with careful patient monitoring. One tablet of Diamicon 60 mg MR is equivalent to 2 tablets of Diamicon 30 mg MR. The breakability of Diamicon 60 mg MR enables flexibility of dosing to be achieved. In patients at risk of hypoglycemia, daily starting dose of 30 mg is recommended. Combination with other antidiabetics: Diamicon 60 mg MR can be given in combination with biguanides, alpha glucosidase inhibitors or insulin (under close medical supervision). •**CONTRAINDICATIONS\*** Hypersensitivity to gliclazide or to any of the excipients, other sulphonylurea or sulphonamides; type 1 diabetes; diabetic pre-coma and coma, diabetic keto-acidosis; severe renal or hepatic insufficiency (in these cases the use of insulin is recommended); treatment with miconazole (see interactions section); lactation (see fertility, pregnancy and

lactation section). •**WARNINGS\*** Hypoglycemia may occur with all sulphonylurea drugs, in cases of accidental overdose, when calorie or glucose intake is deficient, following prolonged or strenuous exercise and in patients with severe hepatic or renal impairment. Hospitalization and glucose administration for several days may be necessary. Patient should be informed of the importance of following dietary advice, of taking regular exercise and of regular monitoring of blood glucose levels. Risk of dysglycaemia in association with fluoroquinolones. To be prescribed only in patients with regular food intake. Use with caution in patients with G6PD-deficiency. Excipients: contains lactose. •**INTERACTION(S)\*** Risk of hypoglycemia – contraindicated: miconazole; not recommended: phenylbutazone; alcohol; use with caution: other antidiabetic agents, beta-blockers, fluconazole, ACE inhibitors (captopril, enalapril), H2-receptor antagonists, MAOIs, sulfonamides, clarithromycin, NSAIDs. Risk of hyperglycaemia – not recommended: danazol; use with caution: chlorpromazine at high doses; glucocorticoids; ritodrine; salbutamol; terbutaline, Saint John's Wort (hypericum perforatum) preparations. Risk of dysglycaemia – use with caution: fluoroquinolones. Potentiation of anticoagulant therapy (e.g. warfarin), adjustment of the anticoagulant may be necessary. •**PREGNANCY\*** Change to insulin before a pregnancy is attempted, or as soon as pregnancy is discovered. •**BREASTFEEDING\*** contra-indicated. •**FERTILITY\*** •**DRIVING & USE OF MACHINES\*** Possible symptoms of hypoglycemia to be taken into account especially at the beginning of the treatment. •**UNDESIRABLE EFFECTS\*** Hypoglycemia, abdominal pain, nausea, vomiting, dyspepsia, diarrhea, constipation. Rare: changes in haematology generally reversible (anaemia, leucopenia, thrombocytopenia, granulocytopenia). Raised hepatic enzymes levels (AST, ALT, alkaline phosphatase), hepatitis (isolated reports). If cholestatic jaundice: discontinuation of treatment. Transient visual disturbances at start of treatment. More rarely: rash, pruritus, urticaria, angioedema, erythema, maculopapular rashes, bullous reactions such as Stevens-Johnson syndrome and toxic epidermal necrolysis, and exceptionally, drug rash with eosinophilia and systemic symptoms (DRESS). As for other sulphonylureas: observed cases of erythrocytopenia, agranulocytosis, haemolytic anaemia, pancytopenia, allergic vasculitis, hyponatraemia, elevated liver enzymes, impairment of liver function (cholestasis, jaundice) and hepatitis which led to life-threatening liver failure in isolated cases. •**OVERDOSE\*** Possible severe hypoglycemia requiring urgent IV glucose, immediate hospitalization and monitoring. •**PROPERTIES\*** Diamicon 60 mg MR is a sulphonylurea reducing blood glucose levels by stimulating insulin secretion from beta cells in the islets of Langerhans, thereby restoring the first peak of insulin secretion and increasing the second phase of insulin secretion in response to a meal or intake of glucose. Independent haemovascular properties. •**PRESENTATION\*** Box of 30, 90 or 100 tablets of Diamicon 60 mg MR in blister. In case of an adverse drug reaction or special situation\* associated with any other medicinal product you should inform national Pharmacovigilance center, Fax: +966-11-2038222, Call NPC at +966-11-203822, ext: 2317-2356-2354-2334-2340 / Toll free phone: 8002490000, e-mail: npc.drug@sfd.gov.sa, website: www.sfd.gov.sa, for SERVIER products, please contact Pharmacovigilance department of SERVIER KSA by e-mail (mohamed.alotaibi@servier.com) or by fax (0112886811) or by phone (0112886813 ext. 101). \*Special situations include: overdose (whether accidental or intentional), abuse, misuse, off-label use, medication error, lack of efficacy, exposure during pregnancy or breastfeeding, occupational exposure, quality defect or falsified medicinal product, suspected transmission via a medicinal product of an infectious agent.